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Registration Standard for the Reregistration of Pesticide Products Containing Methomyl as the Active Ingredient. (Second Round Review)

(U.S.) Environmental Protection Agency, Washington, DC

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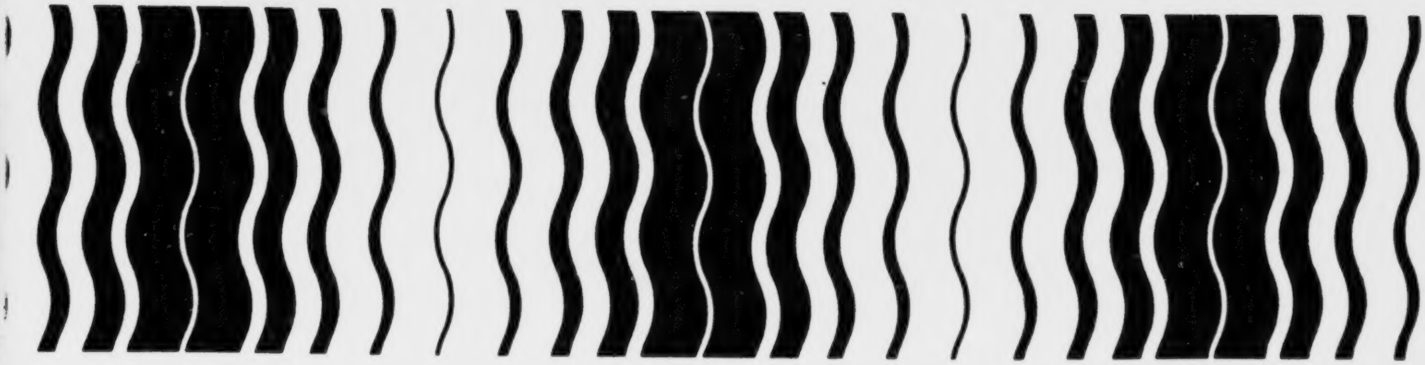
EPA

Registration Standard For Pesticide Products Containing METHOMYL As The Active Ingredient



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REGISTRATION STANDARD
(SECOND ROUND REVIEW)

FOR THE

REREGISTRATION OF PESTICIDE PRODUCTS

CONTAINING

METHOMYL

AS THE ACTIVE INGREDIENT

CAS. NO.: 16752-77-5

OPP Chemical Code 090301

EPA CASE NUMBER 0028

April, 1989

ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF PESTICIDE PROGRAMS

WASHINGTON, D.C. 20460

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GLOSSORY OF TERMS AND ABBREVIATIONS

ADI:	Acceptable Daily Intake
a.i.:	Active Ingredient
CAS:	Chemical Abstract Services (Number)
CSF:	Confidential Statement of Formula
EPA:	The U.S. Environmental Protection Agency (The Agency)
FIFRA:	The Federal Insecticide, Fungicide, and Rodenticide Act
LC50:	Median Lethal Concentration- a statistically derived concentration of a substance that can be expected to cause death in 50% of test animals, expressed as weight or volumn of test substance per volumn of air or water or per weight of feed (e.g., mg/l or ppm).
LD50	Median Lethal Dose- a statistically derived single dose that can be expected to cause death in 50% of test animals when administered by the route indicated, expressed as weight of substance per weight of test animal (e.g., mg/kg).
LEL:	Lowest Effect Level
MPI:	Maximum Permissible Intake
MIRD:	Master Record Identification (Number)- EPA's system of tracking studies used in support of registration.
NPDES:	National Pollution Discharge Elimination System
NOEL:	No Observed Effect Level
OPP:	The Office of Pesticide Programs of the U.S. EPA
PPM:	Parts Per Million
Technical:	Active Ingredient as Manufactured

I. INTRODUCTION

This document is a revised Registration Standard for the subject chemical. In its original Standard, issued in 1981, the Agency summarized the available data supporting the registration of the pesticide and its assessment of those data to determine whether the pesticide met the "no unreasonable adverse effects" standard of FIFRA. The Agency concluded that additional data were necessary to fully evaluate the pesticide, and, as part of the issuance of the Standard, required that registrants supply those data. The Standard also set out labeling requirements that the Agency believed were necessary to ensure that products containing the pesticide were adequate to protect public health and the environment while the data were under development.

The Agency has since reviewed the additional data and has updated and revised its scientific and regulatory conclusions concerning the pesticide in light of expanded data requirements promulgated in 1984 as 40 CFR Part 158. The Registration Standard contains the Agency's updated scientific assessment[1] of this pesticide and its currently registered uses. As part of its review, the Agency has reassessed the tolerances for the pesticide and determined whether they are adequate. The tolerance reassessment is included in this Registration Standard.

Based on the new data, the Agency has also reviewed the labeling requirements for the pesticide and is requiring label revisions.

This revised Registration Standard supersedes the original Registration Standard in its entirety.

This document contains the following sections:

° Section II describes the particular pesticide(s) covered by this Registration Standard, and gives a brief profile of its usage and composition. Regulatory history may be provided as well.

° Section III sets out the Agency's scientific assessment of the health risks and environmental characteristics and effects of the chemical, updated based on data submitted to the Agency under the original Registration Standard.

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[1] The scientific reviews and Compendium of Acceptable Uses are now available from the Freedom Operation Division (H7506C). Write to Office of Pesticides Program, EPA, Washington, DC 20460.

° Section IV explains the regulatory decisions and conclusions arising from the Agency's assessment, and the rationales for its decisions. Section V describes the labeling statements required for products containing the chemical. These are divided into statements for manufacturing use products and statements for end use products.

° Sections VI, VII, VIII, IX and X describe what products are subject to the data and labeling requirements set out in this Registration Standard, and what is required of registrants to comply with the requirements.

° Appendix I contains a series of tables setting out data requirements for the chemical. The tables identify which requirements have been satisfied, as well as those for which gaps remain. A Guide to Tables introduces the tables.

° Appendix II is a series of labeling information sheets, setting out general labeling information that must be placed on labeling.

° Appendix III is a bibliography of the data evaluated by the Agency in its assessment. A Guide to Bibliography explains how to read and use the Bibliography.

° Appendix IV contains the necessary forms to respond to receipt of the Standard

Registrants are reminded that FIFRA sec. 6(a)(2) requires them to submit factual information concerning possible unreasonable adverse effects of a pesticide at any time that they become aware of such information. Registrants must notify the Agency of any information, including interim or preliminary results of studies, if that information suggests possible adverse effects on man or the environment. This requirement is independent of the specific time requirements imposed by EPA for submission of completed studies called in by the Agency and continues as long as the products are registered under FIFRA.

II. CHEMICAL COVERED BY THIS STANDARD

A. Description of Chemical

The following pesticide chemical is covered by this revised Registration Standard:

Generic Name: S-methyl N-[(methylcarbamoyl)oxy]-thioacetimidate

Common Name: Methomyl

Trade Name and other names: methyl N-[[(methylamino)carbonyl]oxy]-ethanimidothioate, methyl N-[(methylcarbamoyl)oxy]-thioacetimidate, Lannate, Lanox, and Nudrin

EPA Shaughnessy Number: 090301

Chemical Abstracts Service (CAS) Number: 16752-77-5

Physicochemical Characteristics:

Technical Methomyl

Color: White
Physical State: Crystalline solid
Melting Point: 78-79 C
Solubility: 5.8 g/100 g water, 100 g/100 g methanol, 72 g/100 g acetone, 42 g/100 g ethanol, 22 g/100 g isopropanol, 3 g/100 g toluene. (no temperature provided)
Vapor pressure: 5 x 10^{-5} mm Hg at 25 C
Specific gravity: 1.2946
Octanol/water partitioning coef: 1.29-1.33[c] at 20 C and 1.08 (no temp. given)

B. Use Profile

Type of Pesticide: Insecticide

Pests Controlled: Broad range of agricultural insects. Control of house flies.

Registered uses: Methomyl is registered on a wide range of field crops, vegetables, fruits, and ornamentals (refer to Table II for a listing of tolerances). It is used in both human and animal premises.

Predominate Uses: Soybeans, peanuts, cotton, tobacco, and corn comprised 80% of the total usage up until 1980. Since then, notable increases have occurred in apples and potatoes.

Mode of Activity: Inhibits the enzyme acetyl cholinesterase

Method of Application: Foliar and soil applications with both ground and aircraft equipment.

Formulations: Wettable powders, emulsifiable concentrates, soluble concentrates, granulars, baits, and dusts.

Basic Registrant: E.I. duPont de Nemours and Company

Year of Initial Registration : 1968

Pesticide Type: Insecticide

Chemical Family: Carbamate

Application rates: 0.1 to 1.5 lb a.i. per acre

Methomyl is formulated in combination with acephate, *Bacillus thuringiensis var. kurstaki*, cryolite, maneb, methyl parathion, and tricosene. Single active ingredient formulations consist of 1 to 2% baits, 1 to 5% granulars and dusts, 1% ready-to-use liquids, 1.8 to 2.4 lb/gal emulsifiable concentrate (EC), 90% wettable powders (WP). Methomyl is usually foliarly applied using ground equipment or aircraft.

The federal and Special Local Need (24 c's) registrations for methomyl include the following:

Section 3 registrations - 33 products - 19 companies

Special Local Need Section 24(c) registrations - 199

III. AGENCY ASSESSMENT

A. SUMMARY

The Agency has reviewed the available data relating to methomyl. Based on the available data, the Agency has arrived at the conclusions summarized below. A detailed discussion of these points can be found in the remaining sections of the "Agency Assessment" portion of this Standard.

1. Acute toxicity: Technical methomyl is highly toxic to laboratory mammals by the oral route of exposure and moderately toxic by dermal exposure. The compound is also a pulmonary irritant.

2. Subchronic Dermal (21 day): The previously submitted study has been downgraded to supplementary. The Agency is requiring another 21-day dermal study testing on both abraded and unabraded skin measuring plasma and red blood cell cholinesterase as an additional endpoint.

3. Chronic toxicity: Chronic feeding studies in the rat and dog show dose-related histopathology effects of the kidney and spleen. The No Observed Effect Level (NOEL) in both the rat and dog is 100 ppm or 2.5 mg/kg/day. Methomyl is not oncogenic in rats or mice.

4. Metabolism: The metabolism of methomyl in plants has been satisfactorily elucidated. Additional metabolism studies in both food producing and non-food producing animals are required. A metabolism study in a food producing animal (cattle) is required to determine the metabolites present with particular attention paid to acetamide. Two metabolism studies, one in the rat and one in the monkey, are required to determine the potential tissue levels of acetamide, a suspected oncogen. Acetamide is a known metabolite of thiodicarb, a related pesticide that breaks down initially to methomyl in non-food species.

5. Adverse Impact on Birds and Aquatic Organisms: Methomyl may have an adverse impact on fish and other aquatic organisms and birds. Aquatic and terrestrial field studies are required to determine the potential risks to these species.

6. Preliminary data indicate a potential groundwater contamination problem. Groundwater monitoring data are required.

7. Methomyl meets the toxicity and exposure criteria defined under the Pesticide Assessment Guidelines, Subdivision K, for reentry. Reentry intervals of from one to seven days are being imposed based upon the available data. These reentry intervals are found in section IV "Regulatory Position and Rationale" part D. "Labeling". Spray drift and droplet size spectrum are required to evaluate the droplet spectra that are associated with actual use patterns.

The Agency has identified the data it believes are necessary to fully evaluate the human and environmental risks associated with the use of methomyl. These data must be submitted in order to maintain registration of products or to register new products containing methomyl. A summary of these data gaps appears below in Table I. Please note that this is only a summary and that complete details must be obtained by referring to the tables in Appendix I.

The Agency has also determined that certain label restrictions and revisions are necessary. Refer to Section IV.D for these revisions.

TABLE I. DATA GAPS

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85-1 General Metabolism

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72-1 Freshwater Fish LC_{50}
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72-3 Acute LC_{50} Estuarine and Marine Organisms
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163-2 Volatility (Lab)
164-2 Aquatic (sediment)
165-4,-5 Accumulation Studies
Groundwater Monitoring
Reentry Data

RESIDUE CHEMISTRY

171-4 Animal Metabolism
Analytical Methods
Residue Data

PRODUCT CHEMISTRY

Product Chemistry Data

B. TOXICOLOGICAL ASSESSMENT

Acute Toxicity

a. Acute oral toxicity

Technical methomyl was administered in fasted laboratory rats of the ChR-CD (Charles River-Caesarian derived/delivered) strain. The LD50 for male rats is 17 mg/kg and for the females is 24 mg/kg, with confidence limits of 14-20 and 22-25 mg/kg, respectively. Based on this study the product was classified as highly toxic and placed in Toxicity Category I for this route of exposure.

b. Acute dermal toxicity

Technical methomyl was applied at a dose of 5000 mg/kg to the intact skin of six male albino rabbits for 24 hours. No observed toxic effects were noted. On the basis of this study, the product was placed in Toxicity Category III.

c. Acute Inhalation Toxicity

Sufficient data are available on the acute inhalation toxicity of methomyl. The LC50 value for aerosolized methomyl is 0.3 mg/liter/4 hours in male ChR-CD rats, Toxicity Category II. Methomyl was found to be a pulmonary irritant.

d. Acute Delayed Neurotoxicity

The available data show that methomyl does not cause delayed neurotoxicity. No evidence of leg or wing paralysis was noted and the pathological examination revealed no abnormalities.

No data are available for primary eye and dermal irritation or skin sensitization. These data are required.

Subchronic Toxicity

No acceptable subchronic oral studies are available; however, adequate chronic feeding studies in both the rat and dog are available and these were used to evaluate the subchronic toxicity in these species. No additional subchronic studies are required.

A subchronic study conducted with Charles River CD rats at doses of 0, 10, 50 125 and 500 ppm produced growth depression and reduced hemoglobin in rats fed diets containing methomyl at a concentration of 125 ppm for three months. No adverse treatment related effects were noted at 50 ppm. This study and others available to the Agency are not acceptable based on modern standards of testing.

A three-month Beagle dog study which was conducted at doses of 0, 10, 100 and 400 ppm reported no evidence of toxicity in levels up to and including 400 ppm (the highest concentration tested, HDT). These data are not adequate because of insufficient reporting of details of animal maintenance, lack of statistical analysis, and absence of histopathologic evaluation.

A 21-day subchronic dermal toxicity study is available using a 90% soluble concentrate. Methomyl was administered dermally to New Zealand albino rabbits with intact or abraded skin at a single dose of 200 mg/kg, 5 days a week, for three weeks. There were no toxic signs noted in the animals with intact skin. However, methomyl was absorbed through abraded skin and caused severe toxic effects (e.g., tremors, labored breathing, miosis, loss of reflexes and hyperactivity). This study was considered acceptable in the original methomyl Registration Standard but is now considered supplementary. The current Pesticide Assessment Guidelines (see 40 CFR §§ 158.20 (d) and 158.70) require a limit dose of 1000 mg/kg on intact (non-abraded) skin.

A study using both abraded and unabraded skin which measures plasma and red blood cell cholinesterase as an additional endpoint is now required. The abraded skin requirement has been added because the Agency feels that this study more closely approximates the exposure conditions experienced by farmworkers.

Chronic Toxicity

Sufficient data are available on the chronic toxicity of methomyl in both the rodent and non-rodent.

In a twenty-two month feeding study using ChR-CD rats, methomyl was fed at dietary concentrations of 0, 50, 100, 200, and 400 ppm. No adverse effects were noted at the 50 or 100 ppm levels. In both male and female rats, the 400 ppm level caused compound-related histopathological alterations in the kidneys, characterized by vacuolation of the tubular epithelial cells and hypertrophy of the convoluted tubules. Compound related histopathologic changes were also seen in the spleen of female rats at doses of 200 to 400 ppm. The No Observable Effect Level (NOEL) was set at 100 ppm.

In a twenty-four month ChR-CD rat study, animals were dosed with technical methomyl at concentrations of 0, 50, 100, and 400 ppm. No treatment-related effects were reported at levels up to and including 100 ppm. However, at 400 ppm, erythrocyte counts, hemoglobin levels and hematocrit values were significantly reduced in females. No significant effects were found with respect to red blood cell (RBC) or brain cholinesterase activity; however, plasma cholinesterase activity was not determined and it is unclear whether animals were fasted prior to the blood and tissue collection. The NOEL for this study was 100 ppm.

In a twenty-four month chronic feeding study in the Beagle dog, four males and four females per dose group were fed methomyl at concentrations of 0, 50, 100, 400 and 1000 ppm. Dose-related histopathology was observed in the kidney and spleen of the 400 and 1000 ppm dose group and in the liver and bone marrow of the 1000 ppm dose group. The NOEL was 100 ppm.

Oncogenicity

Sufficient data are available on the oncogenic potential of methomyl.

ChR-CD rats were fed the test material at doses of 0, 50, 100, 200, and 400 ppm for 22 months. The neoplastic lesions in the high-level test rats were generally comparable with those of the control animals. No oncogenic effects related to treatment were noted. These results were corroborated in a second oncogenicity study where ChR-CD rats were fed methomyl at the same dietary concentrations as the above study.

Methomyl was not oncogenic in mice. Mice were fed dietary concentrations of 0, 50, 75, and 200 ppm. The neoplastic lesions reported were of the usual type and number observed in mice of this age and strain and were essentially comparable in incidence between control and treated groups.

Available animal metabolism data on thiodicarb, a related insecticide that breaks down initially to methomyl, revealed the presence of a minor metabolite acetamide. Acetamide has been characterized as a possible human carcinogen. The Agency is requiring new animal metabolism studies to allow it to address its concerns regarding acetamide.

Teratogenicity

Sufficient data are available to assess the teratogenic potential of methomyl in the rat and rabbit.

Pregnant rats were fed a diet containing 0, 50, 100, and 400 ppm of methomyl on gestation days 6 through 15. Other than maternal body weight loss, there were no dose related effects. Methomyl was neither embryotoxic or teratogenic.

New Zealand White pregnant rabbits were given technical methomyl at dosages of 0, 2, 6, and 16 mg/kg/day on gestation days 7 through 19. Methomyl was not embryotoxic or teratogenic.

Reproduction

Sufficient data are available on the reproductive toxicity of methomyl in the rat.

Methomyl was added to the diets of one month old ChR-CD rats (male and female) for approximately 3 months at dosage levels of 0, 50, and 100 ppm. After completion of this initial feeding study, a reproduction study was conducted with 10 male and 20 female rats. Offspring from these adults were bred in groups to produce F_{2A} and F_{2B} litters. This procedure was followed with the F_{2B} litter to produce F_{3A} and F_{3B} litters. Ten male and 10 female weanling rats from the F_{3B} litter (from the control and each test group) were subjected to a histopathologic evaluation following necropsy.

Methomyl fed to rats at dietary levels of 50 and 100 ppm for 3 generations caused no adverse effect on reproduction nor any gross or histologic evidence of compound-related congenital abnormalities. The NOEL was 100 ppm.

Mutagenicity

Sufficient data are available on the mutagenic potential of methomyl by tests on; 1) gene mutation, 2) structural chromosome aberrations and 3) other mutagenic mechanisms as deemed appropriate. No evidence of mutagenicity was noted in any of the required testing.

Metabolism

No valid metabolism study is available. Rat and monkey metabolism studies are required to assess the tissue levels of acetamide, a possible human oncogen.

C. ECOLOGICAL ASSESSMENT

Avian Toxicity

An acute oral avian study indicates that methomyl is highly toxic to upland game birds. The LD50 value for the bobwhite quail is 24.2 mg/kg.

Subacute dietary toxicity studies on mallard ducks and bobwhite quail indicate that methomyl is slightly toxic, with LC50 values of 2883 and 1100 ppm, respectively.

Maximum application rates for methomyl range from 0.125-0.9 lbs/acre. Estimated foliar residues calculated from using the highest application rate (0.9) immediately following a single application would be 13 to 220 ppm, well below the LC50 values for the mallard duck and bobwhite quail. Even after 7 repeat applications of the highest application rate there is very little risk to avian species on a dietary basis.

The greatest hazard to avian species is expected to be from the ingestion of methomyl treated granules. Agency calculations indicate that the ingestion of as little as 19 granules of 5% granular product can be fatal to small seed eating birds such as the Grasshopper sparrow. The Agency is requiring actual field testing with birds to support the use of 5% granular products.

There are no adequate data for assessing the likelihood of chronic effects. Experimental data on the effects of methomyl on avian reproduction are being required.

Aquatic Organism Toxicity

Acute toxicity data indicate that methomyl is moderately to highly toxic to both cold and warm water fish species (LC50's = 1.6 to 0.5 ppm) and very highly toxic to aquatic invertebrate species (LC50's = 0.07 to 0.34 ppm). Therefore, the Agency is particularly concerned about the direct and indirect hazards that the use of methomyl poses to freshwater aquatic organisms. The use sites which the Agency considers of primary concern are: watercress, citrus, cotton, tobacco, sweetcorn, peanuts amd forest woodlots/plantations, where direct contamination, drift, runoff or soil erosion of methomyl to lakes, streams, ponds or other bodies of water and wetlands may occur.

The Agency's estimated environmental concentrations (EEC's) indicate that the direct application, runoff, drainage, and drift of methomyl into both freshwater and marine environments, when used according to recommended label rates, result in exposures to aquatic organisms that exceed the lower LC_{50} aquatic values discussed above.

The Agency is requiring simulated (e.g., mesocosm), and/or actual field testing, or field monitoring studies to ascertain the potential impact of methomyl in aquatic environments.

Endangered Species

Sufficient data exists to indicate that the current registered use patterns of methomyl may pose a hazard to certain fish, aquatic organisms and insects. The risk levels for birds, reptiles and mammals are apparently not exceeded. In aquatic environments, all maximum application rates for various uses are expected to result in EEC's above the invertebrate LC_{50} and above 1/20 of the fish LC_{50} values for the tested species.

Hazards to Non-Target Insect-Pollinators

The available data indicates that methomyl is highly toxic to bees. The Agency is requiring a bee caution on all end-use products (except granulars) intended for outdoor use.

D. ENVIRONMENTAL FATE ASSESSMENT

Under aerobic conditions, methomyl degrades to predominately CO_2 with a half-life of 30-45 days. Methomyl is relatively stable to hydrolysis under neutral and acidic condtions and degrades under basic conditions with a half-life of 30 days.

Under anaerobic conditions, although acetonitrile is the major degradate in the early stages, CO_2 is the end product, with total conversion in about 8 days. Methomyl is very mobile in sandy loam and silty clay loam soils.

There are confirmed detections of methomyl in groundwater at maximum concentrations of 9 ppb and 1.2 ppb, respectively in New York and New Jersey (EPA's Pesticide Monitoring Inventory Data Base). These levels are not expected to produce acute toxicity effects in humans and therefore, the Agency is not requiring that a groundwater advisory statement be added to methomyl labeling. Additional groundwater monitoring data are required to determine methomyl's impact to ground water.

Although spray drift has been a concern to the Agency, the requirements for these data were not in place at the time of the original Registration Standard for methomyl in 1981. The spray drift requirements are now being imposed.

E. PESTICIDE INCIDENT REPORTS

Data on occupational illness due to methomyl exposure have been received by California, which requires that physicians report all such illnesses to the State. Between 1982 and 1986, physicians treated an average of 11.8 methomyl poisonings per year. An additional 5.4 cases per year were reported as due to skin or eye injuries. Between 1980 and 1886, there were 17 reported hospital-ized cases of occupational methomyl poisoning, the third highest number for any pesticide in California. Thirty-nine workers were off the job for a total of 140 days during this period.

The California data represent a complete count or census of all occupationally related cases. These data indicate that methomyl poses a significant hazard to mixers, loaders, applicators and field workers. From the California census, there were 0.6 poisonings per 1,000 applications. The average value for all 54 pesticides used during this period was 0.8, with a median of 0.4. On the basis of poisonings per pounds sold, there were 6 occupational poisonings per million pounds. For all pesticides this ratio was 1.3.

Reentry Intervals

Because of the above incident reports, California established a reentry interval of two days for citrus, grapes, nectarines and peaches (California Administrative Code, January 4, 1979, Article 23, 2479(h), Field Worker Safety). In its original methomyl Registration Standard, the Agency adopted the two day reentry interval for these crops following California's example and requested that additional reentry data be submitted. The Agency has evaluated the reentry data it has received and has concluded that the following reentry intervals are appropriate: one day for beans, cabbage, roses grown outdoors, and carnations whether grown outdoors or in a greenhouse; three days for cotton, nectarines, and citrus; four days for peaches; and seven days grapes. Additional reentry data are needed for mint, roses grown in greenhouses, and chrysanthemums grown in greenhouses or outdoors. Weight/area conversion factors are required for corn foliage to set an adequate reentry interval to protect workers during detasseling operations.

F. RESIDUE DATA

The nature of the residue in plants is adequately known. Methomyl is converted to methomyl oxime which is subsequently degraded to acetonitrile and carbon dioxide. Methomyl may also be oxidized to methomyl sulfoxide. Recently available data on the metabolism of thiodicarb in plants (thiodicarb, a related pesticide, is metabolized initially to methomyl), reveal that acetamide will not occur in plants following treatment with either thiodicarb or methomyl. Furthermore, any acetamide formed from acetonitrile is hydrolyzed to acetic acid and incorporated into natural products.

The nature of the residue in animals is not adequately understood. The only available ruminant metabolism study (a goat study) failed to characterize 14C-activity. Also, the detection of acetamide in a thiodicarb animal metabolism study raised Agency concerns about the metabolism of methomyl in animals. Additional animal metabolism studies have been required in a Sec. 3(c)(2)(B) Notice issued on March 23, 1987.

Although adequate methods for data collection and enforcement of tolerances are available (Method I. in the PAM, Vol. II. and FDA Multiresidue Protocol No. III), the Agency now requires that all FDA multiresidue methods be tested to determine their adequacy. Therefore, the residues of methomyl occurring in or on raw agricultural plant commodities must be subjected to analysis by multiresidue Protocols I, II, and IV. Also, if the requested data on animal metabolism indicate that residues of toxicological concern occur in tissues, milk, or eggs, methods for data collection and enforcement will be required. Representative samples from the metabolism studies in which [1-14C] methomyl is used, must be subjected to analysis using Method I in the PAM, Vol. II.

Residues of methomyl are stable in plant commodities during long-term storage at near-freezing and sub-freezing temperatures. The nature of the residue in animals is not adequately understood. If the requested data on animal metabolism indicate the presence of residues of toxicological concern, data depicting the stability of those residues in tissues, milk, eggs during frozen storage will be required.

Also, the following conclusions pertaining to tolerances have been reached:

1. On receipt of the required residue chemistry data for members of the root and tuber and bulb vegetable groups, individual tolerances must be established and the current tolerance for residues in or on "root crop vegetables" must be revoked.

2. Residue data and a tolerance proposal are required for dried peas, and the current tolerance for residues in or on "peas" must be revised to "peas plus pod, succulent" on receipt of the requirements for dried peas.

3. Residue data and a tolerance proposal (or a feeding restriction) are required for bean hay.

4. Tolerances (or feeding restrictions) must be proposed

for residues in or on the hay of lentils, peas, and soybeans. The required data for bean hay will be translated to these crops.

5. A tolerance (or a feeding restriction) of 10 ppm for residues in or on lentil forage must be proposed based on the currently available bean forage data.

6. The use of bean forage and hay data for lentil forage and hay will require the establishment of a pregrazing interval of greater than 3 days and a preharvest interval of greater than 7 days.

7. Toxicological considerations permitting, the tolerance for residues in grapes must be increased to greater than or equal to 10 ppm or the PHI must be increased such that residues will not exceed the established tolerances.

8. Residue data and tolerance proposals (or feeding restrictions) are required for sorghum fodder and hay.

9. Additional residue data and tolerance proposals are needed for the forage and hay of clover which is grown for seed.

10. Additional residue data are required for hops.

F. TOLERANCE REASSESSMENT

Tolerances Issued

Tolerances have been established for methomyl on a variety of raw agricultural commodities (see 40 CFR 180.253 and Table II). There are no tolerances established for animal products (meat, milk, poultry and eggs). The need for these tolerances will depend on the results of the requested animal metabolism studies.

Additional data are required to support the following tolerances: apples, chicory leaves, corn grain, corn fodder, cottonseed, onions (dry-bulb), pears, sugar beet tops, sweet potatoes, turnip tops and hops. Data depicting the potential concentration of methomyl residues are required for the processed commodities of corn grain, citrus, cottonseed, peanuts, potatoes, sorghum, soybeans, tomatoes, and wheat. Data depicting the pyrolysis products of methomyl in tobacco smoke are also required.

Dietary Exposure

The Agency has established a Acceptable Daily Intake (ADI) at 0.025 mg/kg/day based on a 2-year dog feeding study (NOEL of 100 ppm) in which histological changes in the kidney and spleen were noted. The Anticipated Residue Contribution (ARC) to the human diet was calculated by factoring the published tolerances by percent of the crops treated. The ARC for the United States population is 0.006677 mg/kg/day which occupies 26.71% of the ADI. The two highest calculated exposures were non- nursing infants less than one year of age (0.018078 mg/kg/day, 72.3% of the ADI) and children 1-6 years old (0.010772 mg/kg/day, 43.1% of the ADI).

TABLE II
SUMMARY OF TOLERANCES

	Tolerances (ppm)			(MRL)
Commodity	[a] U.S.	Canadian	Mexican	Codex
Beets, garden	0.2	-	-	-
Carrots	0.2	-	0.2	-
Chicory	0.2	-	-	-
Horseradish	0.2	-	-	-
Jerusalem artichoke	0.2	-	-	-
Potatoes	0.2	0.1	0.2	0.1
Radishes	0.2	-	-	-
Sugar beet roots	0.2	0.1	-	0.1
Sweet potatoes	0.2	-	-	-
Turnips	0.2	-	-	-
Beet greens	6.0	-	-	-
Sugar beet tops	0.2	-	-	-
Turnip tops	6.0	-	-	-
Garlic	0.2	-	0.2	-
Onions green	3.0	-	-	0.5
Onions bulb	0.2	-	-	0.5
Celery	3.0	0.5	3.0	3.0
Dandelions	6.0	-	-	-
Endive (escarole)	5.0	-	-	-
Lettuce	5.0	2.0	5.0	5.0
Parsley	6.0	0.1	-	-
Spinich	6.0	-	6.0	5.0
Swiss chard	6.0	-	-	-
Broccoli	3.0	0.1	3.0	-
Brussels sprouts	2.0	0.1	-	-
Cabbage	5.0	5.0	5.0	5.0
Cauliflower	2.0	0.1	-	1.0*
Chinese cabbage	5.0	-	-	-
Collards	6.0	-	-	-
Kale	6.0	-	-	5.0*
Mustard greens	6.0	-	-	-
Beans, succulent	2.0	0.1	2.0	2.0*
Beans, dry	0.1	0.1	0.1	0.1*
Lentils	0.1	-	-	-
Peas	5.0	0.1	-	5.0#
Soybeans	0.2	-	0.2	0.1
Bean forage	10.0	-	10.0	-
Pea vines	10.0	-	-	10.0*
Soybean forage Hay and Straw	10.0	-	10.0	10.0*
Eggplant	0.2	-	0.1	0.5*
Peppers	2.0	-	0.2	0.1*
Tomatoes	1.0	0.1	0.2	1.0*
Cucumbers	0.2	-	0.2	0.5*
Melons	0.2	-	0.2	0.2*
Squash	0.2	-	0.2	0.2*
Grapefruit	2.0	1.0	2.0	2.0*
Lemons	2.0	1.0	2.0	2.0*
Oranges	2.0	1.0	2.0	2.0*
Tangerines	2.0	1.0	2.0	2.0*

TABLE II
SUMMARY OF TOLERANCES (con't)

	Tolerances (ppm)			(MRL)
Commodity	[a] U.S.	Canadian	Mexican	Codex
Apples	1.0	0.5	1.0	2.0*
Pears	4.0	-	-	-
Peaches	5.0	-	-	5.0*
Blueberries	6.0	-	-	-
Grapes	5.0	4.0	5.0	5.0*
Strawberries	2.0	-	-	-
Pecans	0.1	-	0.1	-
Barley, Oats and Rye grains	1.0	-	-	-
Corn grain	0.1	-	0.1	-
Corn, fresh	0.1	0.1	0.1	-
Sorghum grain	0.2	-	0.2	0.2*
Wheat grain	1.0	0.1	0.1	0.1*
Forage, hay, and Straw of barley, oats and rye	10.0	-	-	10.0*
Corn forage and Fodder	10.0	-	10.0	-
Sorghum forage	1.0	-	1.0	10.0*
Wheat forage, hay and Straw	10.0	-	6.0	10.0
Bermuda grass	10.0	-	-	-
Bermuda grass hay	40.0	-	-	-
Alfalfa	10.0	-	10.0	10.0*
Asparagus	2.0	-	2.0	2.0*
Avocados	2.0	-	-	-
Cottonseed	0.1	-	0.1	0.1
Hops	7.0	-	-	-
Mint hay	2.0	-	-	0.2*
Peanuts and hulls	0.1	-	-	0.1*
Peanut forage	5.0	-	-	5.0*
Pomegranates	0.2	-	-	-
Watercress	6.0	-	-	-

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a=The U.S., Canadian, and Mexican tolerances and the Codex Maximum Residue Levels (MRL's) expressed in terms of residues of methomyl *per se*.

* These codex MRL's are pending.

# There is a 0.5 ppm codex MRL for peas, shelled.

IV. REGULATORY POSITION AND RATIONALE

A. REGULATORY POSITIONS AND RATIONALES

Based on review and evaluation of all available data and other relevant information on methomyl, the Agency has made the following determinations:

1. Special Review.

The Agency is not now placing methomyl into Special Review. The Agency has insufficient information at this time to determine whether the criteria for initiating Special Review at 40 CFR §154.7 are exceeded for methomyl use patterns.

Rationale: Laboratory data, theoretical calculations and modeling indicate that methomyl use patterns could result in residue levels that would exceed risk criteria for mortality to non-target birds and aquatic organisms. Avian and aquatic field studies are required to determine actual residue levels in the affected environments and to assess the potential risks to aquatic and avian species. Additionally, the Agency believes that the restricted use classification for water soluble bags and the more stringent reentry intervals identified in this Standard provides increased mixer/loader and fieldworker protection. The Agency intends, though, to monitor State pesticide incidents monitoring systems to determine the effectiveness of the labeling changes indentified by this Standard and the necessity of further regulatory actions.

2. Aquatic and Avian Field Testing

The Agency is requiring simulated or actual field testing for both terrestrial and aquatic species.

Terrestrial Species. Actual field testing with birds is required to support the continued use of 5% granular end-use products.

Aquatic Species. Aquatic field, mesocosm, or residue monitoring studies are required using a typical end-use product on the following sites: cotton, citrus, tobacco, sweet corn, watercress and forest woodlots.

Rationale: These studies are needed to assess the risks to birds and aquatic organisms and to determine whether additional regulatory actions are warranted.

3. Restricted Use.

In 1978, the Agency, by regulation codified at 40 CFR §162.31, classified all methomyl products except the 1% bait and 90% water soluble bag formulations as restricted use pesticides. The Agency has now determined that the 90%

water soluble bag formulation should also be classified for restricted use only. To remain in compliance with FIFRA, label revisions will be necessary which specify that a certified applicator must be physically present during mixing, loading and application of this and all other restricted use formulations.

Rationale: The Agency believes that the high acute toxicity of the chemical to humans shows the need for a restricted use classification for the 90% water soluble bag formulation. This classification and the other precautions discussed below are not being proposed for the one percent fly bait formulation because the low exposures resulting from the use of such formulations don't warrant this classification or additional precautions.

4. Protective Clothing and Equipment

The Agency will continue to require that labels bear statements requiring the use of protective clothing for workers reentering treated fields, and this protective clothing provision has been upgraded. In addition, the use of human flaggers during aerial application is prohibited unless they are in enclosed vehicles.

Rationale: Because of the high acute toxicity of methomyl, and the relatively high number of reported poisonings, specific protective clothing and equipment and the above prohibition are required to minimize exposure of methomyl to fieldworkers, applicators and flaggers.

5. Reentry Intervals

In order to remain in compliance with FIFRA, the following reentry interval directions must be placed on the labels of all methomyl end use products (except the one percent fly baits): one day for beans, cabbages, roses grown outdoors, and carnations whether grown outdoors or in a greenhouse; three days for cotton, nectarines, and oranges/citrus; four days for peaches; and seven days for grapes. Because of the similarity in the crops for which reentry data were provided, and in the work tasks performed in those crops, a three day reentry interval is being established for apples, and a one day reentry interval for alfalfa, asparagus, broccoli, brussel sprouts, carrots, cauliflower, celery, collards, cucumbers, lettuce, melons, onions, peanuts, peas, peppers, potatoes, sorghum, soybeans, summer squash, spinach, sugar beets, tobacco, and tomatoes. An interim seven day reentry interval is required for corn and a one day reentry interval is being imposed for all other crops and use sites not listed above.

Rationale: The 1981 Registration Standard required that reentry data be submitted and adopted California's two day reentry interval for citrus, grapes, nectarines, and peaches as an interim measure. Based upon the reentry data submitted in response to the 1981 Standard, the Agency is requiring the above reentry intervals. In cases where additional data are needed, the Agency has chosen to set the above interim reentry intervals. Because of the large number of incidents associated with corn detasseling and other tasks related to corn, an interim seven day reentry interval is being required for corn. These interim reentry intervals will remain in effect until the requested data are received and evaluated. A reentry interval for the one percent fly baits is not required because of the low acute toxicity and use patterns which minimize exposure.

6. Tolerance Revisions

Section 180.253 in 40 CFR will be revised as follows:

a. The current tolerance listing for residues in or on "leafy vegetables [except beet tops . . ."] will be revoked and an individual tolerance of 0.2 ppm for residues in or on sugar beets will be established.

Rationale: The current tolerances for residues in or on "leafy vegetables [except beets (tops). . .]" is outdated and currently covers only residues in sugar beet tops. Other leafy vegetable crops included under this old crop grouping have individual tolerances.

b. The tolerances for residues in or on celery, dandelions, endive (escarole), lettuce, parsley, spinach, and Swiss chard will be revoked and replaced with a 6 ppm tolerance on the crop group, leafy vegetables (except Brassica vegetables) in 40 CFR 180.34(f).

Rationale: The available data support this crop group tolerance.

c. The tolerance for residues in or on fruiting vegetables will be revoked and replaced with an individual tolerance of 0.2 ppm for residues in or on eggplant.

Rationale: The crop group tolerance of 0.2 ppm for residues in or on fruiting vegetables is inappropriate. Entries for tomatoes and peppers currently exist in 40 CFR 180.253 (a) at 1 and 2 ppm, respectively. The established tolerance for residues in or on peppers is greater than five times that established for eggplant. Thus, according to 40 CFR 180.34. (f)(5), a crop group tolerance should not be established.

d. The tolerances for residues in or on grapefruit, lemons, oranges, and tangerines will be revoked and replaced with a 2 ppm tolerance on the crop group, citrus fruits in

40 CFR 180.34(f).

Rationale: The available data support this crop group tolerance.

e. The established tolerance for residues in alfalfa will be revoked and replaced with individual tolerances of 10 ppm for residues of methomyl in or on alfalfa forage and alfalfa hay.

Rationale: Alfalfa forage and hay are considered to be individual raw agricultural commodities and require separate tolerances.

f. The designation "N" will be deleted from all entries where it occurs in 40 CFR 180.253.

Rationale: The term "negligible residue", as defined in 40 CFR 180.1 (k)(i), is no longer used by the Agency in conjunction with tolerance expressions because NOELs frequently change as additional data become available.

7. Groundwater Contamination

Groundwater monitoring data are required since the available data indicated a potential ground water contamination problem. The Agency has chosen not to include a groundwater advisory statement on labeling at this time.

Rationale: Methomyl has been detected in two states. Additional groundwater monitoring data are required to determine methomyl's impact on groundwater. A groundwater advisory labeling statement is not warranted because the levels of methomyl detected to date are not toxicologically significant.

8. Toxicology -Metabolism Studies

The Agency is requiring rat and monkey metabolism studies to determine the potential tissue levels of acetamide in non-food producing animals.

Rationale: Acceptable data are not available on the animal metabolism of methomyl. Previously submitted metabolism studies do not meet current Agency Guidelines because results were not reported in sufficient detail, used too few animals of one sex and did not follow excretion for a sufficient interval of time. This rat metabolism study was acceptable in the initial Registration Standard, but now is considered supplementary. The monkey metabolism study is required because the Agency needs a study conducted on a species more closely related to humans in order to assess tissue levels of acetamide, a possible human oncogen.

9. A subchronic 21-day dermal toxicity study using both abraded and unabraded skin which measures plasma and red blood cell chlolinesterase as additional endpoints are required.

Rationale: The requirement for the 21-day dermal toxicity studies are being imposed because the present Guidelines require a limit dose of 1000 mg/kg on intact skin for a dermal study which does not produce toxic effects. However, since fieldworkers often work with exposed and "abraded" skin, the Agency is also requiring a study done with abraded skin.

10. Endangered Species and Bee Caution

The U.S. Fish and Wildlife Service (USFWS) has determined that certain uses of methomyl, including uses on range and pastureland, forests, grain crops, soybeans, sorghum and cotton, may jeopardize the continued existence of endangered species. Fish, other aquatic organisms and insects are at the greatest risk. A program is being developed by the Agency to reduce or eliminate exposure of this chemical to these species. After this program is developed, the Agency will notify registrants of any additional labeling that may be required to remain in compliance with FIFRA. As explained below, the labeling requirements affecting methomyl, e.g. those listed in PR Notices 87-4 and 87-5, have been withdrawn.

In addition, a bee caution is now required on all products except granulars.

Rationale: Methomyl is highly toxic to fish and aquatic organisms and insects, including bees.

In May 1987, EPA issued PR Notices 87-4 and 87-5 in response to an OES finding that certain pesticides, including methomyl, jeopardized the continued existence of endangered species. Methomyl was omitted from the range and pastureland list and the forest list by error. The Agency later withdrew these PR Notices. The Agency will notify registrants of the labeling requirements and other relevant information to protect endangered species.

11. Priority Review of Data

The Agency has identified certain data that will receive priority review when submitted.

Rationale: Certain data are essential to the Agency's assessment of methomyl. A review of these data may indicate the need for further studies which should be initiated as soon as possible (e.g. tiered studies). The following studies have been identified to receive priority review:

158.240 Residue Chemistry
171-4 Nature of the Residue (Metabolism-Livestock and Poultry), Meat/Milk/Poultry and Eggs

158.390 Reentry Protection
132-1 Foliar Dissipation (Re-entry)
201-1 Droplet Size and Drift Field Evaluation

158.340 Toxicology
82-2 21-Day Dermal Toxicity
85-1 General Metabolism

158.490 Ecological Effects
71-4 Avian Reproduction
71-5 Simulated and Actual Field Testing - Birds
72-1 Freshwater Fish Acute Toxicity
72-2 Acute Toxicity - Freshwater Invertebrate - TEP
72-3 Acute Toxicity - Aquatic Estuarine and Marine Organism
72-5 Fish Life Cycle
72-7 Field Testing for Aquatic Organism

158.290 Environmental Fate
162-3 Anaerobic Aquatic
162-4 Aerobic Aquatic
163-2 Volatility (Lab)
164-2 Aquatic (Sediment)
165-5 Accumulation in Aquatic Non-Target Organisms
Groundwater Monitoring

12. The Agency will not establish any food or feed additive regulations for methomyl until issues concerning the metabolism of methomyl are resolved.

Rationale: The available data indicate that animals metabolize methomyl into acetamide which may be oncogenic. The Delaney Clause of the Federal Food, Drug and Cosmetic Act bars substances which induce cancer in man or test animals, with exceptions which may not apply here.

The Agency is requiring the submission of data to determine whether methomyl residues are indeed converted to acetamide in animal species that are used for human food and whether humans are likely to convert methomyl residues to acetamide. The Agency has issued a policy to address Delaney Clause issues regarding pesticides that have produced positive oncogenic responses in chronic animal studies (53 FR 41104, 10/19/88). After metabolism data are reviewed, the Agency will determine whether and how to apply its Delaney Clause policy to methomyl.

13. While data gaps are being filled, currently registered manufacturing-use products (MPs) and end-use products (EPs) containing methomyl may be sold, distrubuted, formulated, and used, subject to the terms and conditions specified in this Standard. Additionally, registrants must provide or agree to develop additional data, as specified in the Data Appendices, in order to maintain existing registrations.

Rationale: Under FIFRA sections 3(c)(2)(B) and 3(c)(7) the Agency may elect not to cancel or withhold registrations if data are missing or inadequate. Issuance of this Standard provides a mechanism for identifying data needs. These data will be reviewed and evaluated, after which the Agency will determine if additional regulatory actions are necessary.

B. CRITERIA FOR REGISTRATION

To be registered or reregistered under this Standard, manufacturing use and end use products must contain this pesticide, bear required labeling, and conform to the product composition, acute toxicity limits, and use pattern requirements listed in this document.

In order to remain in compliance with FIFRA, registrants must comply with all terms and conditions described in this section, including submission of product specific data specified in Appendix I, submission of revised labeling, commitment to fill data gaps on the schedule specfied by the Agency and, when applicable, offer to pay compensation as required by FIFRA sections 3(c)(1)(D) and 3(c)(2)(D), as amended. Registrants of end use products who qualify for the formulator's exemption must submit five (5) copies of the draft labeling incorporating the unique label statements identified in Section D of this document. Registrants of end use products who do not qualify for the formulator's exemption must comply with the terms and conditions set forth above for manufacturing-use registrants.

C. ACCEPTABLE RANGES AND LIMITS

1. Product Composition Standard

To conform to this Standard, manufacturing-use and end use products must contain this pesticide ingredient. Each formulation proposed must be fully described with an appropriate certification of limits, stating maximum and minimum amounts of the active ingredient and the intentionally added inert ingredients. Additionally, all manufacturing-use and end use products not derived from a registered source must declare all impurities found at greater than 0.1 percent.

2. Acute Toxicity Limits

The Agency will consider registration of technical grade, manufacturing-use, and end-use products containing methomyl provided that the product labeling bears appropriate precautionary statements for the acute toxicity category in which each product is placed.

3. Use Patterns

To be registered under this Standard, manufacturing-use products may be labeled for formulation into end-use products only for the sites and uses listed in the Index in Appendix III. The Use Index lists all registered uses, as well as approved maximum application rates and frequencies. However, no use may be included on the label where the registrant fails to agree to comply with the data requirements in Table A for that use pattern.

D. REQUIRED LABELING

All manufacturing-use products and end-use products must bear appropriate labeling as specified in 40 CFR 162.10, PR Notices 83-2 and 83-3, precautions and warnings listed in the Methomyl Use Index (Appendix III), and as indicated below. Appendix II contains additional information on label specifications.

Schedule for these Labeling Requirements

No pesticide product containing methomyl as an active ingredient may be released for shipment by the registrant after May, 1990 unless the product bears an amended label which complies with the specifications of the Standard.

No pesticide product containing methomyl as an active ingredient may be distributed, sold, offered for sale, held for sale, shipped, delivered for shipment, or received and (having so received) delivered or offered to be delivered by any person after May, 1991 unless the product bears an amended label which complies with the specifications of this Standard.

To remain in compliance with FIFRA, all products must have appropriate storage and disposal statements on the label. Refer to Appendix II for the appropriate statements. Additionally, the following ingredient statement must appear on all methomyl product labels:

"INGREDIENT STATEMENT

ACTIVE INGREDIENTS:

Methomyl (S-Methyl-N-[(methylcarbamoyl)oxy]-
thioacetimidate] . . . . %

INERT INGREDIENTS: . . . . %"

MANUFACTURING-USE PRODUCTS

1. The following statements must appear directly beneath the product name:

"An Insecticide for Formulating Use Only"

"Formulators using this product are responsible for obtaining EPA registration of their formulated product"

"For formulation into end-use insecticide products intended only for (list acceptable sites)"

If detailed instructions for formulating are not provided on the label, the following statement must appear:

"Refer to attached Technical Bulletin for formulating and other information."

NOTE: The technical bulletin must be submitted along with the product label for Agency review.

2. The following environmental hazard statement labeling is specified for all manufacturing-use products:

"ENVIRONMENTAL HAZARD STATEMENT

This pesticide is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless this product is specifically indentified and addressed in the NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA."

END-USE PRODUCT PRODUCT LABELING

1. The following reentry interval directions must be placed on the labels of all methomyl end use products (except the one percent fly baits):

"Reentry into treated areas is prohibited for the following time periods after the end of application, unless personal protective clothing and equipment specified on this label for early reentry are worn.

Seven days for corn and grapes; four days for peaches; three days for cotton, nectarines, citrus and apples; and one day for all other crops and use sites. For early reentry before sprays have dried or dust have settled, wear a long-sleeved shirt, long-legged pants, shoes and socks, chemical resistant gloves, face shield or goggles, and NIOSH or MSHA approved respirator. For early re-entry after sprays have dried or dusts have settled, all the above except the respirator must be worn."

2. Restricted Use Statement

The following restricted use statement must appear on the front panel of all methomyl end-use products except the one percent fly baits.

RESTRICTED USE PESTICIDE

Due to High Acute Toxicity to Humans

For retail sale to and use only by certified applicator or persons under their direct supervision and only for those uses covered by the certified applicator's certification. Direct supervision for this product is defined as the certified applicator being physically present during application, mixing, loading, repair and cleaning of application equipment. Commercial certified applicators must also ensure that all persons involved in these activities are informed of the precautionary statements.

3. The following equipment and protective clothing statements are required for all methomyl end-use products except the one percent fly baits and these statements must be placed in the directions for use section of the labeling:

"PERSONAL PROTECTIVE EQUIPMENT

USE ONLY WHEN WEARING THE FOLLOWING PERSONAL PROTECTIVE EQUIPMENT DURING MIXING/LOADING, APPLICATION, REPAIRING AND CLEANING OF MIXING, LOADING, AND APPLICATION EQUIPMENT, AND DISPOSAL OF THE PESTICIDE: longsleeve shirt; long-legged pants; shoes and socks, chemical resistant gloves; face shield or goggles; NIOSH or MSHA approved respirator. During equipment repair and cleaning, the respirator need not be worn.

IF APPLICATION IS PERFORMED USING AN ENCLOSED CAB OR COCKPIT, THE FOLLOWING PROTECTIVE CLOTHING AND EQUIPMENT MAY BE WORN AS AN ALTERNATIVE: long-sleeve shirt and long-legged pants; shoes and socks. All other protective clothing and equipment required for use during application must be available in the cab and must be worn when exiting the cab into treated area. When used for this purpose, contaminated clothing may not be brought back into the cab unless in an enclosure such as a plastic bag.

IMPORTANT! If pesticide comes in contact with skin, wash off with soap and water and contact a physician immediately. ALWAYS WASH HANDS, FACE, AND ARMS WITH SOAP AND WATER BEFORE USING TOBACCO PRODUCTS, EATING, DRINKING, OR TOILETING.

AFTER WORK: Before removing gloves, wash them with soap and water. Take off all work clothes and shoes. Shower using soap and water. Wear only clean clothes when leaving job--do not wear contaminated clothing. Personal clothing worn during work must be stored and laundered separately from protective clothing and household articles. Store protective clothing separately from personal clothing. Clean or launder protective clothing after each use. Respirators must be cleaned and filters replaced according to instructions included with the respirators. Protective clothing and protective equipment heavily contaminated or drenched with methomyl must be destroyed according to state and local regulations. HEAVILY CONTAMINATED OR DRENCHED CLOTHING CANNOT BE ADEQUATELY DECONTAMINATED.

DURING AERIAL APPLICATION, HUMAN FLAGGERS ARE PROHIBITED."

4. The following protective clothing statements are required for one percent bait products and these statements must be placed in the directions for use section of the labeling.

"PERSONAL PROTECTIVE CLOTHING

Use only when wearing the following personal protective clothing during loading, application, repairing and cleaning of application equipment, and disposal of the pesticide: longsleeve shirt; long-legged pants; shoes and socks; gloves.

IMPORTANT! If pesticide comes in contact with skin, wash off with soap and water.

ALWAYS WASH HANDS, FACE, AND ARMS WITH SOAP AND WATER BEFORE USING TOBACCO PRODUCTS, EATING, DRINKING, OR TOILETING."

5. Additional labeling statements that are being required for baits.

"Do not contaminate feed and foodstuffs. Do not apply where poultry or other animals, especially dogs and young calves, can pick it up or lick it.

Do not use in edible product areas of food processing plants, restaurants, or other areas where food is commercially prepared or processed. Do not use in serving areas when food is present."

6. The following environmental hazard statements, to be placed in the environmental hazard section of the label, are required for all end use products:

A. Granulars (which include baits)

"This pesticide is toxic to birds. Collect, cover or incorporate granules spilled on the soil surface. Do not apply directly to water or wetlands (swamps, bogs, marshes, and potholes). Do not contaminate water when disposing of equipment washwaters."

B. Non-Granular

1. Aquatic (Watercress)

"This pesticide is toxic to fish and wildlife. Drift and runoff from treated areas may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water when disposing of equipment washwaters."

2. Terrestrial

"This pesticide is toxic to fish. Do not apply directly to water or wetlands (swamps, bogs, marshes, and potholes). Drift and runoff may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water when disposing of equipment washwaters."

7. All end use products (except granulars and baits) with outdoor crop uses must have the following bee caution and this statement must be placed in the environmental hazard section of the label.

"This product is highly toxic to bees exposed to direct treatment on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds while bees are actively visiting the treatment area."

8. If the directions for use include lentils, the following restrictions must be placed in the directions for use section of the label.

"Do not allow animals to graze in treated areas for three days after treatment. Do not harvest crop for seven days after treatment."

VI. PRODUCTS SUBJECT TO THIS STANDARD

All products containing one or more of the pesticides identified in Section II.A. are subject to certain requirements for data submittal or changes in composition, labeling or packaging of the product. The applicable requirements depend on whether the product is a manufacturing or end use product and whether the pesticide is the sole active ingredient or one of multiple active ingredients.

Products are subject to this Registration Standard as follows:

A. Manufacturing use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV, if they pertain to the manufacturing use product.

2. The data requirements listed in Tables A and B[2].

3. The labeling requirements specified for manufacturing use products in Section IV.

4. Administrative requirements (application forms, Confidential Statement of Formula, data compensation provisions) associated with reregistration.

B. Manufacturing use products containing this pesticide as one of multiple active ingredients are subject to:

1. The data requirements listed in Table A.

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[2] Data requirements are listed in the three Tables in Appendix I of this Registration Standard. The Guide to Tables in that Appendix explains how to read the Tables.

Table A lists generic data requirements applicable to all products containing the pesticide subject to this Registration Standard. Table B lists product-Specific data applicable to manufacturing-use products. The data in Tables A and B need not be submitted by an end-use producer who is eligible for the generic data exemption for that active ingredient.

Table C lists product-specific data applicable to end-use products. The Agency has decided that, in most cases, it will not require the submittal of product-specific data for end-use products at this time. Therefore, most Registration Standards do not contain a Table C.

2. The labeling requirements specified for manufacturing use products in Section IV.

C. End use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV if they pertain to the end use product.

2. If eligible for the generic data exemption[3], the data requirements listed in Table C.

3. If not eligible for the generic data exemption, the data requirements listed in Table A and the data requirements listed in Table C.

4. The labeling requirements specified for end use products in Section IV.

D. End use products containing this pesticide as one of multiple active ingredients are subject to:

1. If not eligible for the generic data exemption, the data requirements listed in Tables A and C.

2. If eligible for the generic data exemption, the data requirements listed in Table C.

3. The labeling requirements specified for end use

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[3] If you purchase from another producer and use as the source of your active ingredient only EPA-registered products, you are eligible for the generic data exemption for generic data concerning that active ingredient (Table A) and product-specific data for the registered manufacturing use product you purchase (Table B).

Two circumstances nullify this exemption:

1) If you change sources of active ingredient to an unregistered product, formulate your own active ingredient, or acquire your active ingredient from a firm with ownership in common with yours, you individually lose the exemption and become subject to the data requirements in Table A.

2) If no producer subject to the generic data requirements in Table A agrees to submit the required data, all end-use producers lose the exemption, and become subject to the data requirements in Table A.

products in Section IV.

VI. REQUIREMENT FOR SUBMISSION OF GENERIC DATA

This portion of the Registration Standard is a notice issued under the authority of FIFRA sec. 3(c)(2)(B). It refers to the data listed in Table A, which are required to be submitted by registrants to maintain in effect the regis-tration of products containing this active ingredient.[4]

A. What are generic data?

Generic data pertain to the properties or effects of a particular active ingredient. Such data are relevant to an evaluation of all products containing that active ingredient regardless of whether the product contains other ingredients (unless the product bears labeling that would make the data requirement inapplicable).

Generic data may also be data on a "typical formulation" of a product. "Typical formulation" testing is often required for ecological effects studies and applies to all products having that formulation type. These are classed as generic data, and are contained in Table A.

B. Who must submit generic data?

All current registrants are responsible for submitting generic data in response to a data request under FIFRA sec. 3(c)(2)(B) (DCI Notice). EPA has decided, however, not to require a registrant who qualifies for the formulator's exemption (FIFRA sec. 3(c)(2)(D) and 40 CFR 152.85) to submit generic data in response to a DCI notice if the registrant who supplies the active ingredient in his product is complying with the data request.

If you are granted a generic data exemption, you rely on the efforts of other persons to provide the Agency with the required data. If the registrants who have committed to generate and submit the required data fail to take appropriate steps to meet the requirements or are no longer in compliance with this data requirements notice, the Agency will consider that both they and you are not in compliance and will normally initiate proceedings to suspend the registrations of both your product(s) and their product(s) unless you commit to submit and submit the required data in the specified timeframe. In such cases, the Agency generally will not grant a time extension for submitting the data.

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[4] Registrations granted after issuance of this Standard will be conditioned upon submittal or citation of the data listed in this Registration Standard.

If you are not now eligible for a generic data exemption, you may qualify for one if you change your source of supply to a registered source that does not share ownership in common with your firm. If you choose to change sources of supply, the Confidential Statement of Formula must identify the new source(s) and you must submit a Generic Data Exemption Statement.

If you apply for a new registration for products containing this active ingredient after the issuance of this Registration Standard, you will be required to submit or cite generic data relevant to the uses of your product if, at the time the application is submitted, the data have been submitted to the Agency by current registrants. If the required data have not yet been submitted, any new registration will be conditioned upon the new registrant's submittal or citation of the required data not later than the date upon which current registrants of similar products are required to provide such data. See FIFRA sec. 3(c)(7)(A). If you thereafter fail to comply with the condition of that registration to provide data, the registration may be cancelled (FIFRA sec. 6(e)).

C. What generic data must be submitted?

You may determine which generic data you must submit by consulting Table A. That table lists the generic data needed to evaluate current uses of all products containing this active ingredient, the uses for which such data are required, and the dates by which the data must be submitted to the Agency.

D. How to comply with DCI requirements.

Within 90 days of your receipt of this Registration Standard, you must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1, enclosed) for each of your products. On that form you must state which of the following six methods you will use to comply with the DCI requirements:

1. You will submit the data yourself.

2. You have entered into an agreement with one or more registrants to jointly develop (or share in the cost of developing) the data, but will not be submitting the data yourself. If you use this method, you must state who will submit the data on which you will rely. You must also provide EPA with documentary evidence that an agreement has been formed which allows you to rely upon the data to be submitted. Such evidence may be: (1) your letter offering to join in an agreement and the other registrant's acceptance of your offer, (2) a written statement by the parties that an agreement exists,

or (3) a written statement by the person who will be submitting the data that you may rely upon its submittal. The Agency will also require adequate assurance that the person whom you state will provide the data is taking appropriate steps to secure it. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or a mechanism to resolve the terms.

If you and other registrants together are generating or submitting requested data as a task force or consortium, a representative of the group should request a Joint Data Submitter Number, as part of your 90-day response. The request must include the following information:

a. A list of the members of the consortium;
b. The name and address of the designated representative of the consortium, with whom EPA will correspond concerning the data;
c. Identity of the Registration Standard containing the data requirement;
d. A list of the products affected (from all members of the consortium); and
e. Identification of the specific data that the consortium will be generating or submitting.

The Agency will assign a number to the consortium, which should be used on all data submittals by the consortium.

3. You have attempted to enter into an agreement to jointly develop data, but no other registrant has accepted your offer. You request that EPA not suspend your registration for non-compliance with the DCI. EPA has determined that, as a general policy, it will not suspend the registration of a product when the registrant has in good faith sought and continues to seek to enter into a data development/cost sharing program, but the other registrants developing the data have refused to accept its offer. [If your offer is accepted, you may qualify for Option 2 above by entering into an agreement to supply the data.]

In order to qualify for this method, you must:

1. File with EPA a completed "Certification of Attempt to Enter into an Agreement with other Registrants for Develop-ment of Data" (EPA Form 8580-6, enclosed).

2. Provide us with a copy of your offer to the other registrant and proof of the other registrant's receipt of your offer (such as a certified mail receipt). Your offer must, at a minimum, contain the following language or its equivalent:

> [Your company name] offers to share in the burden of producing the data required pursuant to FIFRA sec.

3(c)(2)(B) in the [name of active ingredient] Registration Standard upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA sec. 3(c)(2)(B)(iii).

The remainder of your offer may not in any way attempt to limit this commitment. If the other registrant to whom your offer is made does not accept your offer, and if the other registrant informs us on a DCI Summary Sheet that he will develop and submit the data required under the DCI, then you may qualify for this option. In order for you to avoid suspension under this method, you may not later withdraw or limit your offer to share in the burden of developing the data.

In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice in a timely manner. If the other registrant fails to develop the data or for some other reason would be subject to suspension, your registration as well as that of the other registrant will normally be subject to initiation of suspension proceedings, unless you commit to submit and submit the required data in the specified timeframe. In such cases, the Agency generally will not grant a time extension for submitting the data.

4. You request a waiver of the data requirement. If you believe that a data requirement does not (or should not) apply to your product or its uses, you must provide EPA with a statement of the reasons why you believe this is so. Your statement must address the specific composition or use factors that lead you to believe that a requirement does not apply. Since the Agency has carefully considered the composition and uses of pesticide products in determining that a data require-ment applies, EPA does not anticipate that many waivers will be granted. A request for waiver does not extend the time-frames for developing required data, and if your waiver request is denied, your registration may be suspended if you fail to submit the data. The Agency will respond in writing to your request for a waiver.

5. You request that EPA amend your registration by deleting the uses for which the data are needed. You are not required to submit data for uses which are no longer on your label.

6. You request voluntary cancellation of the registration of your product(s) for which the data are needed.

E. Registrant Requests Regarding Data Requirements and Agency Responses

All requests for modification of data requirements (inapplicability, waiver), approval of protocols or protocol changes, or time extensions must be submitted in writing. The original requirement remains in effect unless the Agency has notified you in writing that it has agreed to a change in the requirement. While being considered by the Agency, such requests for changes in the requirements do not alter the original requirements or extend the time allowed for meeting the requirement.

F. Test Protocols and Standards

All studies required under this Notice must be conducted in accordance with test standards outlined in the Pesticide Assessment Guidelines, unless other protocol or standards are approved for use by the Agency in writing. All testing must be conducted in accordance with applicable Good Laboratory Practices regulations in 40 CFR Part 160.

The Pesticide Assessment Guidelines, which are referenced in the Data Tables, are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, VA 22161 (tel: 703-487-4650).

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD-recommended test standards conform to those specified in the Pesticide Data Requirements regulation (Part 158.70). Please note, however, that certain OECD standards (such as test duration, selection of test species, and degradate identification which are environmental fate requirements) are less restrictive than those in the EPA Assessment Guidelines listed above. When using the OECD protocols, they should be be modified as appropriate so that the data generated by the study will satisfy the requirements of Part 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accord with acceptable standards. The OECD protocols are available from OECD, 1750 Pennsylvania Avenue, N.W., Washington, D.C. 20006.

G. Procedures for requesting a change in test protocol.

If you will generate the required data and plan to use test procedures which deviate from EPA's Pesticide Assessment Guidelines or the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit for EPA approval the protocols you propose to use.

You should submit your protocols before beginning testing, because the Agency will not ordinarily accept as sufficient studies using unapproved protocols. A request for protocol approval will not extend the timeframe for submittal of the data, nor will extensions generally be given to conduct studies due to submittal of inappropriate protocols. The Agency will respond in writing to your request for protocol approval or change.

H. Procedures for requesting extensions of time.

If you think that you will need more time to generate the data than is allowed by EPA's schedule, you may submit a request for an extension of time.

EPA will view failure to request an extension before the data submittal response deadline as a waiver of any future claim that there was insufficient time to submit the data. While EPA considers your request, you must strive to meet the deadline for submitting the data.

The extension request should state the reasons why you believe that an extension is necessary and the steps you have taken to meet the testing deadline. Time extensions normally will not be granted due to problems with laboratory capacity or adequacy of funding, since the Agency believes that with proper planning these can be overcome. The Agency will respond in writing to any requests for extension of time.

I. Data Format and Reporting Requirements

All data submitted in response to this Notice must comply with EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice or contained in PR Notice 86-5 (issued July 29, 1986). All studies must be submitted in the form of a final report; a preliminary report will not be considered to fulfill the submittal requirement.

J. Existing stocks provision upon suspension or cancellation.

The Agency has determined that if a registration is suspended for failure to respond to a DCI request under FIFRA sec. 3(c)(2)(B), an existing stocks provision for the registrant is not consistent with the Act. Accordingly, the Agency does not anticipate granting permission to sell or distribute existing stocks of suspended product except in rare circumstances. If you believe that your product will be suspended or cancelled and that an existing stocks provision should be granted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. The following information must be included in any request for an existing stocks provision:

1. Explanation of why an existing stocks provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale or

distribution; and

2. Demonstration that such a provision would be consistent with the provisions of FIFRA.

VII. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

Under its DCI authority, EPA has determined that certain product-specific data are required to maintain your registrations in effect. Product-specific data are derived from testing using a specific formulated product, and, unlike generic data, generally support only the registration of that product. All such data must be submitted by the dates specified in this Registration Standard.

If you have a manufacturing use product, these data are listed in Table B. If you have an end use product, the data are listed in Table C. As noted earlier, the Agency has decided that it will not routinely require product-specific data for end use products at this time. Therefore, Table C may not be contained in this Registration Standard; if there is no Table C, you are not required to submit the data at this time.

In order to comply with the product specific data requirements, you must follow the same procedures as for generic data. See Section VI.D through J. You should note, however, that product chemistry data are required for every product, and the only acceptable responses are options VI.D.1. (submit data) or VI.D.6.(cancellation of registration).

Failure to comply with the product-specific data requirements for your products will result in suspension of the product's registration.

VIII. REQUIREMENT FOR SUBMITTAL OF REVISED LABELING

FIFRA requires each product to be labeled with accurate, complete and sufficient instructions and precautions, reflecting the Agency's assessment of the data supporting the product and its uses. General labeling requirements are set out in 40 CFR 156.10 (see Appendix II - LABELING and SUMMARY). In addition, labeling language specific to products containing this pesticide is specified in Section IV.D of this Registra-tion Standard. Responses to this Registration Standard must include draft labeling for Agency review.

Labeling must be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. Draft labeling must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text.

If you fail to submit revised labeling as required, which complies with 40 CFR 156.10 and the specific instructions in Section IV.D., EPA may seek to cancel the registration of your product under FIFRA sec. 6.

IX. INSTRUCTIONS FOR SUBMITTAL

All submittals in response to this Registration Standard must be sent to the following address:

Document Processing Desk (RS-0028)
Office of Pesticide Programs - H7504C
U.S. Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460

A. Manufacturing Use Products (MUPs) containing the subject pesticide as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit for each product subject to this Registration Standard:

a. Generic Data Exemption Statement (EPA Form 8580-3), if applicable, or the "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1), with appropriate attachments.

b. Confidential Statement of Formula (EPA Form 8570-4).

c. Evidence of compliance with data compensation requirements of FIFRA sec. 3(c)(1)(D). Refer to 40 CFR 152.80-152.99.

2. Within 9 months from receipt of this document you must submit:

a. Application for Pesticide Registration (EPA Form 8570-1).

b. Five copies of draft labeling, including the container label and any associated supplemental labeling.

c. Product Specific Data Report (EPA Form 8580-4).

3. Within the times set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

4. Within the times set forth in Table B, you must submit all product specific data.

B. Manufacturing Use Products containing the subject pesticide in combination with other active ingredients.

1. Within 90 days from receipt of this document, you must submit:

a. Generic Data Exemption Statement (EPA Form 8580-3), if applicable, or the FIFRA sec. 3(c)(2)(B) Summary Sheet, with appropriate attachments (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4)

2. Within 9 months of receipt of this document, you must submit:

Five copies of draft labeling, including the container label and any associated supplemental labeling.

3. Within the time frames set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

4. Within the time frames set forth in Table B, you must submit all product specific data.

C. End Use Products containing the subject pesticide as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit:

a. Generic data exemption Statement (EPA Form 8580-3), if applicable, or the FIFRA Section 3(c)(2)(B) Summary Sheet, with appropriate attachments (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4).

2. Within 9 months from receipt of this document you must submit:

a. Product Specific Data Report (EPA Form 8580-4), if Table C lists required product-specific data.

b. Five copies of draft labeling, including the container label and any associated supplemental labeling.

3. Within the times set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so

that the schedule cannot be met, immediately notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

4. Within the times set forth in Table C, you must submit all product specific data.

D. End Use Products containing the subject active ingredient as one of multiple active ingredients

1. Within 90 days from receipt of this document, you must submit:

a. Generic data exemption Statement (EPA Form 8580-3), if applicable, or the FIFRA Section 3(c)(2)(B) Summary Sheet, with appropriate attachments (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4).

2. Within 9 months from the receipt of this document, you must submit:

Five copies of draft labeling, including the container label and any associated supplemental labeling.

3. Within the times set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

E. Intrastate Products

Applications for full Federal registration of intrastate products were required to be submitted no later than July 31, 1988. Unless an application for registration was submitted by that date, no product may be released for shipment by the producer after July 31, 1988.

I. DATA APPENDICES

TGUIDE-1

GUIDE TO TABLES

Tables A, B, and C contain listings of data requirements for the pesticides covered by this Registration Standard.

Table A contains generic data requirements that apply to the pesticide in all products, including data requirements for which a "typical formulation" is the test substance.

Table B contains product-specific data requirements that apply only to a manufacturing use product.

Table C contains product-specific data requirements that apply only to an end use product.

The data tables are generally organized according to the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. The reference numbers accompanying each test refer to the test protocols set out in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161.

2. Test Substance (Column 2). This column lists the composition of the test substance required to be used for the test, as follows:

TGAI = Technical grade of the active ingredient
PAI = Pure active ingredient
PAIRA = Pure active ingredient, radio labeled
TEP = Typical end use formulation
MP = Manufacturing use product
EP = End use product

Any other test substances, such as metabolites, will be specifically named in Column 2 or in footnotes to the table.

3. Use pattern (Column 3). This column indicates the use patterns to which the data requirement applies. Use patterns are the same as those given in 40 CFR Part 158. The following letter designations are used for the given use patterns:

A = Terrestrial, food
B = Terrestrial, non-food
C = Aquatic, food
D = Aquatic, non-food
E = Greenhouse, food
F = Greenhouse, non-food
G = Forestry
H = Domestic outdoor
I = Indoor

Any other designations will be defined in a footnote to the table.

4. Does EPA have data? (Column 4). This column indicates one of three answers:

> YES - EPA has data in its files that satisfy this data requirement. These data may be cited by other registrants in accordance with data compensation requirements of Part 152, Subpart E.
>
> PARTIALLY - EPA has some data in its files, but such data do not fully satisfy the data requirement. In some cases, the Agency may possess data on one of two required species, or may possess data on one test substance but not all. The term may also indicate that the data available to EPA are incomplete. In this case, when the data are clarified, or additional details of the testing submitted by the original data submitter, the data may be determined to be acceptable. If this is the case, a footnote to the table will usually say so.
>
> NO - EPA either possesses no data which are sufficient to fulfill the data requirement, or the data which EPA does possess are flawed scientifically in a manner that cannot be remedied by clarification or additional information.

5. Bibliographic citation (Column 5). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a GS number if no MRID number has been assigned. Refer to the Bibliography Appendices for a complete citation of the study.

6. Must additional data be submitted? (Column 6). This column indicates whether the data must be submitted to the Agency. If column 3 indicates that the Agency already has data, this column will usually indicate NO. If column 3 indicates that the Agency has only partial data or no data, this column will usually indicate YES. In some cases, even though the Agency does not have the data, EPA will not require its submission because of the unique characteristics of the chemical; because data on another chemical can be used to fulfill the data requirement; or because the data requirement has been waived or reserved. Any such unusual situations will be explained in a footnote to the table.

7. Timeframe for submission (Column 7). If column 5 requires that data be submitted, this column indicates when the data are to be submitted, based on the issuance date of the Registration Standard. The timeframes are those established either as a result of a previous Data Call-In letter, or standardized timeframes established by PR Notice 85-5 (August 22, 1985).

8. Footnotes (at the end of each table). Self-explanatory.

TABLE A
GENERIC DATA REQUIREMENTS FOR METHOMYL

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data? 1/	Bibliographic Citation	Must Additional Data be Submitted? 2/	Time Frame for Submission
§158, Subpart C Product Chemistry						
Product Identity						
61-2 - Description of Beginning Materials and Manufacturing Process	TGAI	All	NO	-	YES2/	9 Months
61-3 - Discussion of Formation of Impurities	TGAI	All	NO	-	YES3/	9 Months
Analysis and Certification of Product Ingredients						
62-1 - Preliminary Analysis	TGAI	All	NO	-	YES4/	12 Months
Physical and Chemical Characteristics						
63-2 - Color	TGAI	All	NO	-	YES5/	9 Months
63-3 - Physical State	TGAI	All	NO	-	YES5/	9 Months
63-4 - Odor	TGAI	All	NO	-	YES5/	9 Months
63-5 - Melting Point	TGAI	All	NO	-	YES5,6/	9 Months
63-6 - Boiling Point	TGAI	All	NO	-	YES5,7/	9 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR METHOMYL

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data? 1/	Bibliographic Citation	Must Additional Data be Submitted? 2/	Time Frame for Submission
§158, Subpart C Product Chemistry (Continued)						
Physical and Chemical Characteristics (Continued)						
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	All	NO	-	YES[5/]	9 Months
63-8 - Solubility	TGAI or PAI	All	NO	-	YES[5/]	9 Months
63-9 - Vapor Pressure	PAI	All	NO	-	YES[5/]	9 Months
63-10 - Dissociation constant	PAI	All	NO	-	YES[5/]	9 Months
63-11 - Octanol/water partition coefficient	PAI	All	NO	-	YES[5,8/]	9 Months
63-12 - pH	TGAI	All	NO	-	YES[5,9/]	9 Months
63-13 - Stability	TGAI	All	NO	-	YES[5/]	9 Months

1/ Although product chemistry data may have been submitted in the past, the Agency has determined that these data must be resubmitted for each pesticide. New requirements have been introduced and previously submitted data must be updated. Therefore, bibliographic citations for the old data are not applicable.

2/ Complete information must be provided regarding the nature and process (batch or continuous), the relative amounts of beginning materials and the order in which they are added, the chemical equations for each intended reaction, equipment used to produce each intermediate and the final product, reaction conditions, the duration of each step of the process, purification procedures, and quality control measures. In addition the name and address of the manufacturer, producer, or supplier of each beginning material used in the manufacture of each product must be provided, along with information regarding the properties of each beginning material used to manufacture each product.

§158, Subpart C Product Chemistry (Continued)

3/ A detailed discussion of all impurities that are or may be present at ≥0.1%, based on knowledge of the beginning materials, chemical reactions (intended and side) in the manufacturing process, and any contamination during and after production must be submitted. This discussion must also address the possible formation of nitrosamine unless the Registrant provides evidence that product containers are free of nitrosating agents.

4/ Five or more representative samples must be analyzed for the amount of active ingredient and each impurity for which certified limits are required. Complete validation data (accuracy and precision) must be submitted for each analytical method used. In addition, unless the Registrant provides evidence that product containers are free of nitrosating agents, all nitrosamines must be identified and quantified in six samples of each product; two samples of each must be analyzed shortly after production, 3 months after production, and 6 months after production. A method sensitive to 1 ppm of N-nitroso contaminants must be used. An upper limit must be provided and certified for all nitrosamines found.

5/ Physicochemical characteristics (color, physical state, odor, melting point, boiling point, specific gravity, solubility, vapor pressure, dissociation constant, partition coefficient, pH, and stability) as required in 40 CFR 158.120 and more fully described in the Pesticide Assessment Guidelines, Subdivision D, must be submitted.

6/ Data are needed if the technical chemical is a solid at room temperature.

7/ Data are needed if the technical chemical is a liquid at roome temperature.

8/ Data are required if the technical chemical is organic and non-polar.

9/ Data are required if the test substance is dispersible with water.

TABLE A
GENERIC DATA REQUIREMENTS FOR METHOMYL

Data Requirement	Test substance	Does EPA have data?	Bibliographic citation	Must additional data be submitted?	Time frame for submission
158.240 Residue Chemistry					
171-2. Chemical Identity[1]					
171-3. Directions for use[2]		(See Index)			
171-4. Nature of the residue (Metabolism) - Plants	PAIRA	YES	00044069, 00135794, 00158689, 05008206	NO	
171-4. Nature of the residue (Metabolism) - Ruminants	PAIRA	PARTIALLY	00063418	YES	March 1989[4a]
- Poultry	PAIRA	NO		YES[3,4]	18 Months
171-4. Residue analytical methods	TGAI	PARTIALLY	00007132, 00009009, 00008837, 00009074, 00085367	YES[5,6]	March 1989[4a]
171-4. Storage stability	TEP and metabolites	PARTIALLY	00007044, 00063421, 00073259, 00144617, 00126579, 05008453	YES[7]	15 Months
171-4. Magnitude of the residue in plants					
Root and Tuber Vegetables -Beets	TEP	YES	00073259	NO	

TABLE A
GENERIC DATA REQUIREMENTS FOR METHOMYL

Data Requirement	Test substance	Does EPA have data?	Bibliographic citation	Must additional data be submitted?	Time frame for submission
158.240 Residue Chemistry (con't)					
-Carrots	TEP	YES	00007837	NO	
-Chicory	TEP	YES	00009063	NO	
-Horseradish	TEP	YES	(see carrots)	NO	
-Jerusalem artichoke	TEP	YES	(see potatoes)	NO	
-Potatoes	TEP	PARTIALLY	00008295, 00008862	YES[8]/	24 Months
-Radishes	TEP	YES	(see carrots)	NO	
-Sugar beet roots	TEP	YES	00007004, 00007161, 00008044	NO	
-Sweet potatoes	TEP	NO		YES[9]/	18 Months
-Turnips	TEP	YES	(see carrots)	NO	
Leaves of Root and Tuber Vegetables					
- Beet greens	TEP	YES	00073259 (also see spinach)	NO	
- Chicory leaves	TEP	NO		YES[10]/	18 Months
- Sugar beet tops	TEP	NO		YES[11]/	18 Months
- Turnip tops	TEP	PARTIALLY	00008362	YES[12]/	18 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR METHOMYL

Data Requirement	Test substance	Does EPA have data?	Bibliographic citation	Must additional data be submitted?	Time frame for submission
Bulb Vegetables					
- Garlic	TEP	NO		YES[13/]	18 Months
- Onions	TEP	PARTIALLY	00007192, 00073261 00144617	YES[14/]	18 Months
Leafy Vegetables					
- Celery	TEP	YES	00007136, 00008679 00008803, 00055457	NO	
- Dandelions	TEP	YES	(see spinach)	NO	
- Endive (escarole)	TEP	YES	(see lettuce)	NO	
- Lettuce	TEP	YES	00007039, 00007168 00007175, 00007715 00007992, 00008264 00008964	NO	
- Parsley	TEP	YES	(see spinach)	NO	
- Spinach	TEP	YES	00007001, 00007002 00007003, 00007185 00055457	NO	
- Swiss chard	TEP	YES	(see spinach)	NO	

TABLE A
GENERIC DATA REQUIREMENTS FOR METHOMYL

Data Requirement	Test substance	Does EPA have data?	Bibliographic citation	Must additional data be submitted?	Time frame for submission
Brassica Leafy Vegetables					
- Broccoli	TEP	YES	00007604, 00008043 00055457	NO	
- Brussels sprouts	TEP	YES	00008043, 00055457	NO	
- Cabbage	TEP	YES	00007039, 00007168 00007715, 00007928 00008679, 00008964	NO	
- Chinese cabbage	TEP	YES	(see lettuce)	NO	
- Cauliflower	TEP	YES	00007605, 00008043 00055457	NO	
- Collards	TEP	YES	00008359, 00008359	NO	
- Kale	TEP	YES	00008360	NO	
- Mustard greens	TEP	YES	00008361	NO	
Legume Vegetables					
- Beans (Phaseolus)	TEP	YES	00007134, 00007135 00007168, 00008264 00008436, 00009154	NO	
- Lentils	TEP	YES	(see beans)	NO	
- Peas	TEP	PARTIALLY	00007683, 00007999, 00008154, 00009079	YES[15/]	18 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR METHOMYL

Data Requirement	Test substance	Does EPA have data?	Bibliographic citation	Must additional data be submitted?	Time frame for submission
- Soybeans	TEP	PARTIALLY	00007008, 00008264, 00008411, 00008602, 00008998, 00009083, 00142925	YES[16/]	24 Months
Foliage of Legume Vegetables Group					
- Bean forage and hay	TEP	PARTIALLY	00007134, 00007168, 00008264, 00009154	YES[17/]	18 Months
- Lentil forage and hay	TEP	NO		YES[18/]	18 Months
- Peas vines and hay	TEP	PARTIALLY	00007683, 00007999, 00008145, 00009079	YES[19/]	18 Months
- Soybean forage and hay	TEP	PARTIALLY	00007008, 00008264, 00008411, 00008602, 00008998, 00009083, 00142925	YES[20/]	18 Months
Fruiting Vegetables (except Cucurbit) Group					
- Eggplant	TEP	YES	00007039, 00009000	NO	
- Peppers	TEP	YES	00006995, 00006996, 00007094, 00009000	NO	
- Tomatoes	TEP	PARTIALLY	00007007, 00007039, 00007094, 00007626, 00008742, 00156940, 05009890	YES[21/]	24 Months

TABLE A

GENERIC DATA REQUIREMENTS FOR METHOMYL

Data Requirement	Test substance	Does EPA have data?	Bibliographic citation	Must additional data be submitted?	Time frame for submission
Cucurbit Vegetables Group					
- Cucumbers	TEP	YES	00007970, 00009076, 00009291	NO	
- Melons	TEP	YES	00007970, 00009291, 00144827	NO	
- Squash	TEP	YES	00007970, 00144827	NO	
Citrus Fruits Group					
- Grapefruit	TEP	YES	00007137, 00007140, 00009070	NO	
- Lemons	TEP	YES	00007138, 00009070	NO	
- Oranges	TEP	PARTIALLY	00007139, 00009070	YES[22]	24 Months
- Tangerines	TEP	YES	00007140	NO	
- Tangelos	TEP	YES	00009070	NO	
Pome Fruits Group					
- Apples	TEP	PARTIALLY	00007077	YES[23]	18 Months
- Pears	TEP	PARTIALLY	00063419, 00063421	YES[24]	18 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR METHOMYL

Data Requirement	Test substance	Does EPA have data?	Bibliographic citation	Must additional data be submitted?	Time frame for submission
Stone Fruits Group					
- Peaches	TEP	YES	00038316, 00144827, 00156939, 00007672, 00007832	NO	
Small Fruits and Berries Group					
- Blueberries	TEP	YES	00008334	NO	
- Grapes	TEP	PARTIALLY	00007634, 00007991, 00144827, 00156973	YES[25]/	18 Months
- Strawberries	TEP	YES	00008847, 00009004	NO	
Tree Nuts Group					
- Pecans	TEP	YES	00008919	NO	
Cereal Grains Group					
- Barley grain	TEP	PARTIALLY	00007612	YES[26]/	24 Months
- Corn	TEP	PARTIALLY	00007039, 00007142, 00007659, 00008838	YES[27]/ YES[28]/	18 Months 24 Months
- Oat grain	TEP	PARTIALLY	00007612	YES[29]/	24 Months
- Rye grain	TEP	PARTIALLY	00007612	YES[30]/	24 Months
- Sorghum grain	TEP	PARTIALLY	00008233, 00009366	YES[31]/	24 Months
- Wheat grain	TEP	PARTIALLY	00007612, 00156941	YES[32]/	24 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR METHOMYL

Data Requirement	Test substance	Does EPA have data?	Bibliographic citation	Must additional data be submitted?	Time frame for submission
Forage, Fodder, and Straw of Cereal Grains Group					
- Barley forage, hay, and straw	TEP	YES	00007612	NO	
- Corn forage and fodder	TEP	PARTIALLY	00007039, 00007142, 00008838, 00073260	YES[33]/	18 Months
- Oat forage, hay, and straw	TEP	YES	00007612	NO	
- Rye forage and straw	TEP	YES	00007612	NO	
- Sorghum forage	TEP	PARTIALLY	00008233, 00009366	YES[34]/	18 Months
- Wheat forage, hay and straw	TEP	YES	00007612, 00156941	NO	
Grass Forage Fodder and Hay Group					
- Bermuda grass	TEP	YES	00050464, 00078359	NO	
Non-grass Animal Feeds Group					
- Alfalfa	TEP	YES	00007133, 00007159, 00008039, 00008984	NO	
- Clover	TEP	NO		YES[35]/	18 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR METHOMYL

Data Requirement	Test substance	Does EPA have data?	Bibliographic citation	Must additional data be submitted?	Time frame for submission
Miscellaneous Commodities					
- Asparagus	TEP	YES	00008938	NO	
- Avocados	TEP	YES	00161144	NO	
- Cottonseed	TEP	PARTIALLY	00007690, 00007989, 00009075, 00009135, 00009378	YES[36/] YES[37/]	18 Months 24 Months
- Hops	TEP	PARTIALLY	40056901	YES[38/]	March 1989
- Mint	TEP	YES	00007043, 00007044, 00007996	NO	
- Peanuts	TEP	PARTIALLY	00007081, 00007997, 00009078,	YES[39/]	24 Months
- Pomegranates	TEP	YES	00009002, 00009003	NO	
- Watercress	TEP	YES	(see spinach)	NO	
- Tobacco	PAIRA	PARTIALLY	00007005, 00008453, 00008964, 00157373, 05008453, 05013872	YES[40/]	18 Months
Magnitude of the Residue					
- Meat/Milk/Poultry/ Eggs	TGAI	PARTIALLY	00008832, 00009365	YES[41,42/]	April 1990

TABLE A
GENERIC DATA REQUIREMENTS FOR METHOMYL

Data Requirement	Test substance	Does EPA have data?	Bibliographic citation	Must additional data be submitted?	Time frame for submission
158.240 Residue Chemistry (con't)					

1/ The same chemical identity data are required as under 158.120, with emphasis on impurities that could constitute residue problems. Refer to Product Chemistry Data Requirements tables.

2/ The maximum number of applications and/or seasonal application rate must be specified on the product labels for alfalfa, anise, apples, asparagus, avocados, barley, beans, beets, Bermuda grass, blueberries, broccoli, Brussels sprouts, cabbage, carrots, cauliflower, celery, chicory, Chinese cabbage, collards, field corn, sweet corn, popcorn, cotton, cucumbers, dandelions, eggplant, endive (escarole), grapefruit, grapes, horseradish, Jerusalem artichoke, kale, lemons, lentils, lettuce, melons, mint, mustard greens, nectarines, oats, onions, oranges, parsley, pasture grass, peaches, pecans, peppers, pomegranates, potatoes, radishes, rye, sorghum, soybeans, spinach, strawberries, summer squash, Swiss chard, tangelos, tangerines, tomatoes, turnips, watercress, and wheat. These restrictions must be supported by the available/requested residue data.

3/ Data are required depicting the metabolism of methomyl in poultry. Animals must be dosed for three days with [1-^{14}C]methomyl at a level sufficient to make residue identification and quantification possible. Eggs must be collected twice daily during the dosing period. Animals must be sacrificed within 24 hours of the final dose. The distribution and characterization of residues must be determined in eggs, liver, kidney, muscle, and fat. Specific analyses for acetamide and acetonitrile must be included. Samples from these studies must also be analyzed by Method I in the PAM, Vol. II, Pest. Reg. Sec. 180.253 to ascertain that the method is capable of adequately recovering and quantifying all residues of toxicological concern.

4/ Data depicting the nature of methomyl residues in swine are also required unless the metabolism of methomyl in ruminants or poultry does not differ significantly from that in rats.

4a/ These data have been submitted recently, and are currently in review.

5/ Residues of methomyl occurring in or on raw agricultural plant commodities must be subjected to analysis by multiresidue Protocols I, II, and IV. These Protocols are available from the National Technical Information Service under Order No. PB 203734/AS.

158.240 Residue Chemistry (con't)

6/ If the requested data on animal metabolism indicate that residues of toxicological concern occur in tissues, milk, or eggs, methods for data collection and enforcement will be required. We have required, in the "Nature of the Residue in Animals" section, that representative samples from the metabolism studies, in which [1-^{14}C]-methomyl is to be used, be subjected to analyses using Method I in the PAM, Vol. II.

7/ If the requested data on animal metabolism indicate the presence of residues of toxicological concern, data depicting the stability of those residues in tissues, eggs, and milk during frozen storage will be required.

8/ Data are required depicting methomyl residues in chips, granules or flakes, and wet and dry potato peel processed from potatoes bearing measurable weathered residues. If residues concentrate in any of these processed commodities, an appropriate food/feed additive tolerance must be proposed. It may be necessary to use exaggerated rates to obtain measurable residues in the raw agricultural commodity.

9/ Data are required depicting residues in or on sweet potatoes grown in CA and harvested 30 days after the last of three aerial applicationns with the 90% SC/S formulation at 1 lb ai/5 gal/A. Alternatively, the 24(c) registration may be voluntarily cancelled.

10/ Data are required depicting residues in or on chicory leaves harvested 80 days after multiple foliar application at 5-day intervals of the 1.8 lb/gal SC/L formulation at 0.9 lb ai/A. Tests must be conducted in MA(6%), NJ(17%), and NY(3%), which collectively accounted for 26% of the 1982 U.S. chicory acreage (1982 Census of Agriculture, Vol. 1, Part 51, p. 341), and represent the major U.S. chicory growing regions.

11/ Data are required depicting residues in or on sugar beet tops harvested 7 days after multiple soil and foliar applications (in the same test) of the 1.5% G and an SC/L or SC/S formulation, respectively, at 0.9 lb ai/A. For foliar treatments, both ground and aerial application data (from separate tests) must be provided. If necessary, an appropriate tolerance increase must be proposed. Also, the 30-day PHI for "tops" must be stricken from the labels. Tests must be conducted in CA(21%), ID(15%), MN(22%), and WY(5%) which together represent 89% of the U.S. sugarbeet crop if MN represents MI(10%), NE(5%) and ND(11%).

12/ Data are required depicting residues of methomyl in or on turnip tops harvested 3 days following the last of two foliar applications of the 90% SC/S formulation at 0.9 lb ai/A. Ground and aerial equipment must be represented in separate tests. Tests must be conducted in CA. Alternatively, the registrant may elect to cancel this use permitted under EPA SLN No. CA770495.

13/ The data required for dry bulb onions will be translated to garlic.

158.240 Residue Chemistry (con't)

14/ Data are required depicting residues of methomyl in or on dry bulb onions harvested 7 days following multiple foliar applications of the 90% SC/S or a SC/L formulation at 0.9 lb ai/A and multiple soil applications of the 1.25% G formulation (in the same field trials) at 0.25 lb ai/A. Tests must be conducted (1) CA(28%), (2) NY(9%), and (3) ID(8%) or OR(15%), states that accounted for 70% of U.S. onion production for storage, non-storage and processing (Agricultural Statistics, 1986).

15/ Data are required depicting residues in dried pea seed harvested 1 day after the last of several soil and foliar applications (in the same test) of a G and SC formulation, respectively, at 0.9 lb ai/A. Tests must be conducted in WI(28%) and WA(17%) which together represent approximately 74% of the U.S. pea crop (for processing) if WI represents MN(22%) and WA represents OR(7%) [Agricultural Statistics, 1986, p. 162]. A tolerance for residues in dried pea seed must be proposed.

16/ Data are required depicting the potential for concentration of residues in meal, soapstock, crude oil, refined oil, and grain dust processed from soybeans bearing measurable, weathered residues. If the data indicate a potential for concentration of residues in any of these processed commodities, an appropriate food/feed additive tolerance must be proposed.

17/ Data are required depicting residues in or on bean hay harvested 7 days after the last of several foliar and soil applications (in the same test) with a SC and G formulation, respectively, at 0.9 lb ai/A. Tests must be conducted in MI(24%), ND(14%), ID(9%), CO(13%) and CA(16%) which together represent approximately 88% of the U.S. bean production area if CO represents NE(12%) [Agricultural Statistics, 1986, p. 252]. For foliar applications, both ground and aerial data, from separate tests, must be submitted. The registrant must propose a tolerance for residues of methomyl in or on bean hay. Alternatively, the registrant may elect to amend all pertinent labels to prohibit feeding of hay.

18/ Tolerances for residues of methomyl in or on lentil forage and hay must be proposed. Also, a pregrazing interval of ≥ 3 days for forage and a preharvest interval of ≥ 7 days for hay must be proposed. These pregrazing/preharvest intervals will allow the Registrant to use the available and requested data for other legumes in support of the proposed tolerances. A tolerance of 10 ppm should be proposed for forage. The appropriate tolerance level for hay will depend on the results of the required data for bean hay. Alternatively, feeding and grazing restrictions for lentil forage and hay may be proposed.

19/ Since pea hay is a raw agricultural commodity of peas, the registrant must propose a tolerance for residues of methomyl in or on pea hay. The required data for bean hay may be translated to pea hay. Alternatively, the registrant may elect to amend all pertinent labels to prohibit feeding of hay.

158.240 Residue Chemistry (con't)

28/ Data are required depicting the potential for concentration of residues in commodities processed from corn grain bearing measurable, weathered residues. Data are required on starch, crude oil, and refined oil from wet milling; grits, meal, flour, crude oil, and refined oil from dry milling; and grain dust. If the data indicate a potential for concentration of residues in any of these commodities an appropriate food/feed additive tolerance must be proposed.

29/ Processing data will be translated from the required data for wheat.

30/ Processing data will be translated from the required data for wheat.

31/ Data are required depicting the potential for concentration of residues in flour, starch, and grain dust processed from sorghum grain bearing measurable, weathered residues. If the data indicate a potential for concentration of residues in either of these commodities, an appropriate food/feed additive tolerance must be proposed.

32/ Data are required depicting the potential for concentration of residues in middlings, shorts, and grain dust derived from wheat grain bearing measurable, weathered residues. If the data indicate a potential for concentration of residues in any of these commodities, appropriate feed additive tolerances must be proposed.

33/ Data are required depicting residues of methomyl in or on corn fodder harvested 3 days following the completion of a treatment schedule that includes foliar application of a G formulation at 1 lb ai/A and foliar applications of the 2.4 lb/gal SC/L formulation at 0.45 lb ai/1 gal/A. Separate test data for aerial and ground applications must be submitted. Tests must be conducted in IL(17%), IA(19%), NE(11%), and MN(8%) which collectively produced ca. 60% of U.S. corn grain in 1985 and represent the major field corn growing regions (Agricultural Statistics, 1986, p. 32).

34/ Data are required depicting residues in or on fodder and hay harvested 14 days after the last of several foliar applictions of a SC formulation at 0.45 lb ai/A. Tests must be conducted in KS(26%) and TX(22%) which together represent 80% of the U.S. sorghum production area if KS represents MO(11%) and NE(14%) and TX represents AR(6%) [Agricultural Statistics, 1986, p. 52]. Tolerances must be proposed. Alternatively, the Registrant may amend all labels to prohibit feeding of sorghum fodder or hay to livestock.

158.240 Residue Chemistry (con't)

35/ Data are required depicting residues of methomyl in or on clover forage and hay harvested immediately following the last of multiple foliar applications of the 90% SC/S formulation at 1 lb ai/A using both ground and aerial equipment in separate tests. The registrant must propose a maximum number of applications per season. The requested data must reflect these proposals. Alternatively, the registrant may elect to cancel this use permitted under EPA SLN No. CA780127.

36/ Data are required depicting residues in or on cottonseed harvested 15 days after the last of several foliar treatments using a D formulation at 1 lb ai/A. Tests must be conducted in CA(23%), MS(12%) and TX(29%) which together produce 64% of the U.S. cotton crop (Agricultural Statistics, 1986, p. 62). An appropriate tolerance increase must be proposed.

37/ Data are required depicting concentration of methomyl residues during processing of cottonseed hulls and soapstock derived from cottonseed bearing measurable weathered residues. (Exaggerated application rates may be necessary to obtain these levels on the cottonseed). If concentration occurs during processing, the registrant must propose appropriate food/feed additive tolerances.

38/ These data were requested in an FR Notice dated Sept. 23, 1987 (52 FR 35730; PP # 7E3495).

39/ Data are required depicting methomyl residues in meal, crude oil, refined oil, and soapstock processed from peanuts bearing measurable weathered residues. If residues concentrate in any of these processed commodities, then appropriate food/feed additive tolerances must be proposed.

40/ Pyrolysis products derived from the active ingredient must be characterized in tobacco smoke. Weathered residues of [14C]methomyl must be used for identification of pyrolysis products.

41/ Additional animal metabolism data have been requested in this document (see "Nature of the Residue in Animals" sections for details). Upon receipt of those data the need for and nature of tolerances for residues of methomyl in meat, milk, poultry, and eggs will be determined and additional feeding studies may be required.

42/ These data were required previously through a Data Call-In notice in March 1987.

TABLE A
GENERIC DATA REQUIREMENTS FOR METHOMYL

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.340 Toxicology						
ACUTE TESTING:						
81-1 - Acute Oral - Rat	TGAI		YES	00009227	NO	
81-2 - Acute Dermal	TGAI		YES	00007947	NO	
81-3 - Acute Inhalation - Rat	TGAI		YES	00008982	NO	
81-7 - Acute Delayed Neurotoxicity - Hen	TGAI		YES	00008827	NO	
SUBCHRONIC TESTING:						
82-1 - 90-Day Feeding -						
Rodent (Rat)	TGAI		NO	-	NO[1/]	
Non-Rodent (Dog)	TGAI		NO	-	NO[2/]	
82-2 - 21-Day Dermal	TGAI	A,B,C E,F,G I	NO	-	YES[3/]	12 Months
82-3 - 90-Day Dermal	TGAI		NO	-	NO[4/]	
82-4 - 90-Day Inhalation - Rat	TGAI		NO	-	NO[4/]	
82-5 - 90-Day Neurotoxicity-Hen/Mammal	TGAI		NO	-	NO[5/]	

TABLE A
GENERIC DATA REQUIREMENTS FOR METHOMYL

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.340 Toxicology (Cont.)						
CHRONIC TESTING:						
83-1 - Chronic Toxicity -						
Rodent (ChR-CD® Rat)	TGAI		YES	00078361	NO	
Non-rodent (Beagle Dog)	TGAI		YES	00007091	NO	
83-2 - Oncogenicity Study -						
(ChR-CD® Rat)	TGAI		YES	00078361	NO	
(Mouse)	TGAI		YES	00078423	NO	
83-3 - Teratogenicity -						
(Rat)	TGAI		YES	00008621	NO	
(Rabbit)	TGAI		YES	00131257	NO	
83-4 - Reproduction, 2-generation	TGAI		YES	00007093	NO	
MUTAGENICITY TESTING						
84-2 - Gene Mutation	TGAI		YES	00161887	NO	
84-2 - Chromosomal Aberration	TGAI		YES	00161888	NO	
84-2 - Other Mechanisms of Mutagenicity	TGAI		YES	05009139	NO	

TABLE A

GENERIC DATA REQUIREMENTS FOR METHOMYL

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.340 Toxicology (continued)						
SPECIAL TESTING						
85-1 - General Metabolism	PAI or PAIRA	A,B,C E,F,G I	NO	-	YES[6/]	24 Months
86-1 - Domestic Animal Safety	Choice		NO	-	NO[4/]	

1/ This requirement is waived based on the submission of an acceptable chronic feeding study in the rat.

2/ This requirement is waived based on the submission of an acceptable chronic feeding study in the dog.

3/ Under the first Standard, MRID No. 00009234 was considered satisfactory. However, this Standard is downgrading this study to supplementary. Guidelines require a limit dose of 1000 mg/kg on intact skin which does not produce toxic effects. In addition, the Agency is requiring testing on both abraded and unabraded skin measuring plasma and red blood cell cholinesterase as an additional endpoint.

4/ This study is not required under the existing use patterns.

5/ Since an acute neurotoxicity study is negative for this compound and there is no evidence of neurotoxicity in mammalian species, this study is not required.

6/ Guideline studies in the rat and monkey are required to determine potential tissue levels of acetamide in non-food animals following ingestion of methomyl.

TABLE A
GENERIC DATA REQUIREMENTS FOR METHOMYL

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.290 Environmental Fate						
DEGRADATION STUDIES-LAB:						
161-1 - Hydrolysis	TGAI or PAIRA	A,B,C,E,F	YES	00131249	NO	
Photodegradation						
161-2 - In water	TGAI or PAIRA	A,B,C	YES	00161885	NO	
161-3 - On soil	TGAI or PAIRA	A	YES	00163745	NO	
161-4 - In air	TGAI or PAIRA		NO	-	Reserved1/	
METABOLISM STUDIES-LAB:						
162-1 - Aerobic Soil	TGAI or PAIRA	A,B,E,F	YES	00008568	NO	
162-2 - Anaerobic Soil	TGAI or PAIRA	A	YES	00073214	NO	
162-3 - Anaerobic Aquatic	TGAI or PAIRA	C	NO	-	YES	27 Months
162-4 - Aerobic Aquatic	TGAI or PAIRA	C	NO	-	YES	27 Months
MOBILITY STUDIES:						
163-1 - Leaching and Adsorption/Desorption	TGAI or PAIRA	A,B,C,E,F	YES	00044306 00161884	NO	
163-2 - Volatility (Lab)	TEP	A,E,F	NO	-	YES	12 Months
163-3 - Volatility (Field)	TEP	A,E,F	NO	-	Reserved1/	

TABLE A
GENERIC DATA REQUIREMENTS FOR METHOMYL

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.290 Environmental Fate - Continued						
DISSIPATION STUDIES-FIELD:						
164-1 - Soil	TEP	A,B	YES	00009326	NO	
164-2 - Aquatic (Sediment)	TEP	C	NO	-	YES	27 Months
164-3 - Forestry	TEP	A	NO	-	NO[2/]	
164-5 - Soil, Long-term	TEP	A	NO	-	NO[3/]	
ACCUMULATION STUDIES:						
165-1 - Rotational Crops (Confined)	PAIRA	A	YES	00019947	NO	
165-2 - Rotational Crops (Field)	TEP	A	NO	-	NO[4/]	
165-4 - Irrigated Crops	TEP	C	NO	-	YES	39 Months
165-4 - In Fish	TGAI or PAIRA	A,B,C	YES	00019947	NO	
165-5 - In Aquatic Non-Target Organisms	TEP		NO	-	YES	12 Months
GROUNDWATER MONITORING	TEP	A,B	NO	-	YES[5/]	27 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR METHOMYL

§158.290 Environmental Fate - Continued

1/ These studies may be required pending results of the laboratory volatility study.

2/ Although there are forestry uses, the application is for ground only, therefore this study is not applicable.

3/ These data are not required because methomyl is not persistant.

4/ As data showed that methomyl did not accumulate in the confined study, a field study is not needed.

5/ Based on the results of the laboratory studies on mobility, additional data are necessary to determine the impact of methomyl on ground water. Therefore, small scale retrospective groundwater field monitoring studies are being required. This type of study evaluates the impact of past (and current) use of a pesticide on ground water beneath, and if appropriate, downgradient of fields with known histories of usage and hydrogeologic vulnerability. A minimum of three field sites will be required. For each site, the study will encompass at least one set of soil samples (to characterize the soil down to the water table and to locate contaminate plumes from recent applications) and several water samples from wells installed for the study. Existing wells may also be used for sampling if properly constructed and they tap appropriate protions of the aquifer. A protocol must be submitted within 90 days from receipt of this notice prior to initiation of the study. This protocol must also propose geographic areas (preferably counties) in which appropriate sites will be located. These areas must be typical of the use sites of methomyl and must be hydrogeologically vulnerable. The proposal must include justification of the proposed area: hydrogeologic vulnerability as evidenced by sandy soils, shallow aquifers and use patterns as evidenced by sales data. In addition, sampling and laboratory methodology (including analytical recovery data) must be included for parent methomyl and degradates.

TABLE A
GENERIC DATA REQUIREMENTS FOR METHOMYL

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.390 Reentry Protection						
132-1 - Foliar Dissipation	TEP	A,B	PARTIALLY		YES[1]	27 Months
132-1 - Soil Dissipation	TEP	A,B	NO	-	NO[2]	
131-3 - Dermal Exposure	TEP	A,B	NO	-	NO[3]	
131-4 - Inhalation Exposure	TEP	A,B	NO	-	NO[3]	
§158.440 Spray Drift						
201-1 - Droplet Size Spectrum	TEP	A,B	NO	-	YES[4]	27 Months
201-1 - Drift Field Evaluation	TEP	A,B	NO	-	YES[4]	27 Months

1/ Data are required for mint, roses grown in greenhouses, chrysanthemums in greenhouses or outdoors and the weight/area conversion factors (used in the data previously submitted) for corn foliage. For each end-use, the registrant is required to propose an acceptable reentry interval based either upon data: (a) on dissipation of residues (decline curve), on human exposure to those residues, and on toxicity of the residues; or (b) on determination of that time beyond which there are no detectable dislodgeable or inhalable residues remaining in the worker/occupant environment. If the registrant has reason to believe that an end-use product will not cause exposure to residues, a request for waiver from this data requirement must be submitted.

2/ Soil dissipation data are required only for uses where workers will be exposed directly to substantial quantities of soil during their work activities, e.g. for use on potatoes or peanuts where hand harvesting will be performed.

3/ Human exposure monitoring data may be submitted at the registrant's option. However, if dermal exposure data are submitted, then inhalation data must also be submitted.

4/ The spray drift droplet spectrum and field evaluation may be done together in order to evaluate the droplet spectrums that are associated with actual field use patterns.

TABLE A
GENERIC DATA REQUIREMENTS FOR METHOMYL

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.490 Wildlife and Aquatic Organisms						
TERRESTRIAL ORGANISMS						
71-1 Avian single dose oral LD_{50}	TGAI	A,B,G,I	YES	00161886	NO	
71-2 Avian Dietary LC_{50}						
a. upland game bird	TGAI	A,B,G,I	YES	00062189 00022923	NO	
b. waterfowl	TGAI	A,B,G	YES	00062189	NO	
71-3 Wild Mammal	TGAI	A,B,G	YES		NO[1/]	
71-4 Avian Reproduction	TGAI	A,B,G	NO		YES[2/]	24 Months
71-5 Simulated and Actual Field Testing for Mammals and Birds	TEP (5% granular)	A,B,G	NO		YES[3/]	48 Months
AQUATIC ORGANISMS						
72-1 Freshwater Fish LC_{50}						
a. warmwater	TGAI	A,B,G,I	YES	40094602	NO	
b. coldwater	TGAI	A,B,G	YES	40094602	NO	
c. warmwater	TEP	A,B,G	PARTIALLY	40094602 00077273	YES[4/]	9 Months
d. coldwater	TEP	A,B,G	PARTIALLY	40094602 00077272 00009226 00077271	YES[4/]	9 Months
e. warmwater	DEGRADATE	A,B,G	YES	00009061	NO	
72-2 Acute LC_{50} Freshwater Invertebrate	TGAI	A,B,C,G,I	YES	00019977, 00034016	NO	
	TEP	A,B,C,G	PARTIALLY	40094602	YES4/	9 Months

TABLE A

GENERIC DATA REQUIREMENTS FOR METHOMYL

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.490 Wildlife and Aquatic Organisms (Cont.)						
72-3 Acute LC_{50} Estuarine and Marine Organisms						
a. Shrimp	TGAI	A,B	NO		YES[5]/	12 Months
	TEP	A,B	PARTIALLY	00009134	YES[5],[4]/	12 Months
		A,B		00009230		
b Fish	TGAI	A,B	NO		YES[5]	12 Months
	TEP	A,B	NO		YES[5],[4]/	12 Months
c. Mollusk	TGAI	A,B	NO		YES[5]	12 Months
	TEP	A,B	NO		YES[5],[4]/	12 Months
72-4 Fish and Early Life-Stage Aquatic Invert. Life-Cycle	TGAI	A,B,C,G	YES	00131255	NO	
	TGAI	A,B,C,G	YES	00131254	NO	
72-5 Fish Life-Cycle	TEP	A,B,C,G	NO		YES[6]/	27 Months
72-6 Aquatic Organism Accumulation	TEP	A,B,C	YES		NO	
72-7 Simulated/Actual Field Testing of Aquatic Organisms or Residue Monitoring	TEP	A,B,C	NO		YES[7]/	48 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR METHOMYL

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.490 Wildlife and Aquatic Organisms (Cont.)						

1/ The Agency will use toxicology data to satisfy this requirement.
2/ This study is required because the use directions call for repeat applications.
3/ Actual field testing (Level 1) with birds is required, as per 40 CFR 158.145, to support the use of end-use products containing the 5% granular formulation. Initial sites to be tested, based upon application rates and wildlife usage information include; field corn and sorghum (broadcast applications). The design of the field study must include appropriate methods such as thorough carcass searching to determine whether there is a pesticideinduced mortality and, if so, to what extent. Protocols for these field studies must be submitted to the Agency for review within 90 days from receipt of the standard. A Guidance Document is available, from the Agency, which outlines an acceptable approach to these studies. The Agency encourages the registrants to consult with our staff for assistance as needed.
4/ Testing is being required for the emulsifiable concentrate formulation.
5/ Testing is being required in shrimp, fish and mollusk to support cotton, citrus and peanut uses (crops exceeding 300,000 acres in coastal counties).
6/ Test are required because estimated environmental concentrations are equal to or greater than 1/10 of the no-effect level in the fish early life-stage or invertebrate life cycle test.
7/ Aquatic field studies, mesocosm studies and/or the option to conduct residue monitoring studies are required for the cotton, citrus, tobacco, sweet corn, watercress and forest woodlot uses. Field studies for other use patterns are reserved pending an evaluation of the results for these crops and an analysis of their applicability to support other uses. Study protocols for each study must be submitted to the Agency. For either mesocosm or actual aquatic field studies, the study design must include appropriate techniques to determine acute mortality to aquatic invertebrates and effects on productivity and diversity of fish. A protocol for a mesocosm or full field study must be submitted to the Agency for review within 90 days from receipt of the standard. A guidance document is available, from the Agency, which outlines an acceptable approach to mesocosm studies. This document also provides relevant, although general, guidance for full field studies, which, if selected in place of the mesocosm studies, must include multiple treated ponds and control ponds. The Agency encourages registrants to consult with the our staff for assistance as needed.

TABLE A
GENERIC DATA REQUIREMENTS FOR METHOMYL

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.540 Plant Protection						
121-1 - TARGET AREA PHYTOTOXICITY	EP		NO	-	NO	Reserved[1]
NONTARGET AREA PHYTOTOXICITY						
TIER I						
122-1 - Seed Germination/ Seedling Emergence	TGAI		NO	-	NO	Reserved[1]
122-1 - Vegetative Vigor	TGAI		NO	-	NO	Reserved[1]
122-2 - Aquatic Plant Growth	TGAI		NO	-	NO	Reserved[1]
TIER II						
123-1 - Seed Germination/ Seedling Emergence	TGAI		NO	-	NO	Reserved[1]
123-1 - Vegetative Vigor	TGAI		NO	-	NO	Reserved[1]
123-2 - Aquatic Plant Growth	TGAI		NO	-	NO	Reserved[1]
TIER III						
124-1 - Terrestrial Field	TEP		NO	-	NO	Reserved[1]
124-2 - Aquatic Field	TEP		NO	-	NO	Reserved[1]

1/ These data are not required in accordance with §158.150.

TABLE A
GENERIC DATA REQUIREMENTS FOR METHOMYL

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.590 Nontarget Insect						
NONTARGET INSECT TESTING - POLLINATORS:						
141-1 - Honey bee acute contact toxicity	TGAI	A,B,G,H	YES	05011163	NO	
141-2 - Honey bee - toxicity of residues on foliage	TEP	A,B,G,H	YES	00014715 05000837	NO	
141-4 - Honey bee subacute feeding study	(Reserved)1/					
141-5 - Field testing for pollinators	TEP	A,B,G,H	NO		NO2/	
NONTARGET INSECT TESTING - AQUATIC INSECTS:						
142-1 - Acute toxicity to aquatic insects	(Reserved)3/					
142-1 - Aquatic insect life-cycle study	(Reserved)3/					
142-3 - Simulated or actual field testing for aquatic insects	(Reserved)3/					
143-1 thru 143-3 - NONTARGET INSECT TESTING - PREDATORS AND PARASITES	(Reserved)3/					

TABLE A
GENERIC DATA REQUIREMENTS FOR METHOMYL

§158.540 and §158.590 Plant Protection and Nontarget Insect - Continued

1/ Reserved pending development of methodology.
2/ This requirement is imposed on a case-by-case basis. Data reviewed under this standard do not indicate the need for a field study.
3/ Reserved pending Agency decision as to whether the data requirement should be established.

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING METHOMYL

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?[1/]	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158, Subpart C - Product Chemistry						
Product Identity:						
61-1. Product Identity and Disclosure of Ingredients	MP	ALL	NO	-	YES[2/]	9 Months
61-2 - Description of Beginning Materials and Manufacturing Process	MP	ALL	NO	-	YES[3/]	9 Months
61-3 - Discussion of Formation of Impurities	MP	ALL	NO	-	YES[4/]	9 Months
Analysis and Certification of Product Ingredients						
62-1 - Preliminary Analysis	MP	ALL	NO	-	YES[5/]	12 Months
62-2 - Certification of Limits	MP	ALL	NO	-	YES[6/]	12 Months
62-3 - Analytical Methods to Verify Certified Limits	MP	ALL	NO	-	YES[7/]	12 Months
Physical and Chemical Characteristics						
63-2 - Color	MP	ALL	NO	-	YES[8/]	9 Months
63-3 - Physical State	MP	ALL	NO	-	YES[8/]	9 Months
63-4 - Odor	MP	ALL	NO	-	YES[8/]	9 Months
63-7 - Density, Bulk Density or Specific Gravity	MP	ALL	NO	-	YES[8/]	9 Months

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING METHOMYL

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?[1]	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158, Subpart C - Product Chemistry (cont.)						
63-12 - pH	MP	ALL	NO	-	YES[8],9/	9 Months
62-14 - Oxidizing or Reducing Action	MP	ALL	NO	-	YES[8],10/	9 Months
62-15 - Flammability	MP	ALL	NO	-	YES[8],11/	9 Months
63-16 - Explodability	MP	ALL	NO	-	YES[8],12/	9 months
63-17 - Storage Stability	MP	ALL	NO	-	Yes[8]/	15 months
63-19 -Miscibility	MP	ALL	NO	-	YES[8],13/	9 months
63-20 -Corrosion Characteristics	MP	ALL	NO	-	YES[8],14/	15 months
Other Requirements:						
64-1 - Submittal of Samples	N/A	N/A	N/A	-	NO	

1/ Although product chemistry data may have been submitted in the past, the Agency has determined that these data must be resubmitted for each pesticide. New requirements have been introduced and previously submitted data must be updated. Therefore, bibliographic citations for the old data are not applicable.

2/ The chemical name, nominal concentration, Chemical Abstracts (CAS) Registry Number, and purpose of the active ingredient and each intentionally added inert must be provided. For the active ingredients, the following must also be provided: the product, common, and trade names; the molecular, structural, and empirica formulas; the molecular weight or weight range; and any experimental or internally assigned company code numbers.

3/ Complete information must be provided regarding the nature and process (batch or continuous), the relative amounts of beginning materials and the order in which they are added, the chemical equations for each intended reaction, equipment used to produce each intermediate and the final product, reaction conditions, the duration of each step of the process, purification procedures, and quality control measures. In addition the name and address of the manufacturer, producer, or supplier of each beginning material used in the manufacture of each product must be provided, along with information regarding the properties of those materials.

4/ A detailed discussion of all impurities that are or may be present at ≥0.1%, based on knowledge of the beginning materials, chemical reactions (intended and side) in the manufacturing process, and any contamination during and after production must be submitted. This discussion must also address the possible formation of nitrosamines unless the Registrant provides evidence that product containers are free of nitrosating agents and no nitrosating agents are added during formulation.

5/ Five or more representative samples must be analyzed for the amount of active ingredient and each impurity for which certified limits are required. Complete validation data (accuracy and precision) must be submitted for each analytical method used. In addition, unless the Registrant provides evidence that product containers are free of nitrosating agents and no nitrosating agents are added during formulation, all nitrosamines must be identified and quantified in six samples of each product; two samples of each must be analyzed shortly after production, 3 months after production, and 6 months after production. A method sensitive to 1 ppm of N-nitroso contaminants must be used. An upper limit must be provided and certified for all nitrosamines found.

6/ Upper and lower limits for the active ingredient and each intentionally added inert, and upper limits for each impurity present at ≥0.1% (w/w) and each "toxicologically significant" impurity present at <0.1% (w/w) must be provided and certified. Also, an explanation of how each certified limit was established must be provided (e.g., sample analysis using validated analytical procedures, quantitative estimate based on amounts of ingredients used, etc.). Limits for impurities not associated with the active ingredient need be provided only if they are considered to be of toxicological significance, regardless of the concentration at which they are present Certifications must be submitted on EPA Form 8570 Rev. 2-85.

7/ Analytical methods must be provided to determine the active ingredient, and each toxicologically significant impurity and intentionally added inert for which certified limits are required. Each method must be accompanied by validation studies indicating its accuracy and precision. These methods must be suitable for enforcement of certified limits.

8/ Physicochemical characteristics (color, physical state, odor, specific gravity, pH, oxidizing or reducing action, flammability, explodability, storage stability, viscosity, miscibility, and corrosion characteristics) as required in 40 CFR 158.120 and more fully described in the Pesticide Assessment Guidelines, Subdivision D, must be submitted.

9/ Data required if the test substance is dispersible in water.

10/ Data required if the product contains oxidizing or reducing agents.

11/ Data required if the product contains combustible liquids.

12/ Data required if the product is potentially explosive.

13/ Data required if the product is a liquid.

14/ Data required if the product is a liquid and is to be diluted with petroleum solvents.

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING METHOMYL

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data? /1	Bibliographic Citation	Must Additional Data be Submitted? 1/	Time Frame for Submission
§158.340 Toxicology						
ACUTE TESTING:						
81-1 - Acute Oral Toxicity - Rat	MP[2]	All	Partially	00009227	YES[1]	9 Months
81-2 - Acute Dermal Toxicity - Rabbit	MP	All	Partially	00007947	YES[1]	9 Months
81-3 - Acute Inhalation Toxicity - Rat	MP	All	Partially	00008982	YES[1]	9 Months
81-4 - Primary Eye Irritation - Rabbit	MP	All	NO	-	YES[1]	9 Months
81-5 - Primary Dermal Irritation - Rabbit	MP	All	NO	-	YES[1]	9 Months
81-6 - Dermal Sensitization - Guinea Pig	MP	All	NO	-	YES[1]	9 Months

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1/ Data are adequate to support registration of MP products containing 90% TGAI. Data are required for all other MP formulations.

2/ Formulation intermediates are also included in the category of manufacturing-use products.

II. LABELING APPENDICES

SUMMARY-1

LABEL CONTENTS

40 CFR 156.10 requires that certain specific labeling statements appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to the table at the end of this Appendix.

Item 1. PRODUCT NAME - The name, brand or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading.

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text.

Item 3. NET CONTENTS - A net contents statement is required on all labels or on the container of the pesticide. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label test. The net contents must be expressed in the largest suitable unit, e.g., "1 pound 10 ounces" rather than "26 ounces." In addition to English units, net contents may be expressed in metric units. [40 CFR 156.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. [40 CFR 156.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment number on the immediate container cannot be clearly read through such wrapper or container. [40 CFR 156.10(f)]

Item 6A. INGREDIENTS STATEMENT - An ingredients statement is required on the front panel. The ingredients statement must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredients statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. [40 CFR 156.10(g)]

Item 6B. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - Front panel precautionary statements must be grouped together, preferably within a block outline. The table below shows the minimum type size requirements for various size labels.

Size of Label on Front Panel in Square Inches	Signal Word Minimum Type Size All Capitals	"Keep Out of Reach of Children" Minimum Type Size
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - The statement "Keep Out of Reach of Children" must be located on the front panel above the signal word except where contact with children during distribution or use is unlikely. [40 CFR 156.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (DANGER, WARNING, or CAUTION) is required on the front panel immediately below the child hazard warning statement. [40CFR 156.10(h)(1)(i)]

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, dermal, or inhalation toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word POISON. [40 CFR 156.10(h)(1)(i)

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. [40 CFR 156.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "see Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. [40 CFR 156.10(h)(1)(iii)]

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. [40 CFR 156.10(h)(2)]

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. [40 CFR 156.10(h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. [40 CFR 156.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD - FLAMMABILITY Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in the PHYS/CHEM Labeling Appendix. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

Item 9A. RESTRICTED USE CLASSIFICATION - FIFRA sec. 3(d) requires that all pesticide formulations/uses be classified for either general or restricted use. Products classified for restricted use may be limited to use by certified applicators or persons under their direct supervision (or may be subject to other restrictions that may be imposed by regulation).

In the Registration Standard, the Agency has (1) indicated certain formulations/uses are to be restricted (Section IV indicates why the product has been classified for restricted use); or (2) reserved any classification decision until appropriate data are submitted.

The Regulatory Position and Rationale states whether products containing this active ingredient are classified for restricted use. If they are restricted the draft label(s) submitted to the Agency as part of your application must reflect this determination (see below).

If you do not believe that your product should be classified for restricted use, you must submit any information and rationale with your application for reregistration. During the Agency's review of your application, your proposed classification determination will be evaluated in accordance with the provisions of 40 CFR 162.11(c). You will be notified of the Agency's classification decision.

Classification Labeling Requirements

If your product has been classified for restricted use, the following label requirements apply:

1. All uses restricted.

   a. The statement "Restricted Use Pesticide" must appear at the top of the front panel of the label. The statement must be set in type of the same minimum size as required for human hazard signal word (see table in 40 CFR 156.10(h)(1)(iv).

   b. Directly below this statement on the front panel, a summary statement of the terms of restriction must appear (including the reasons for restriction if specified in Section I). If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification."

2. Some but not all uses restricted. If the Regulatory Position and Rationale states that some uses are classified for restricted use, and some are unclassified several courses of action are available:

   a. You may label the product for Restricted use. If you do so, you may include on the label uses that are unrestricted, but you may not distinguish them on the label as being unrestricted.

   b. You may delete all restricted uses from your label and submit draft labeling bearing only unrestricted uses.

c. You may "split" your registration, i.e., register two separate products with identical formulations, one bearing only unrestricted uses, and the other bearing restricted uses. To do so, submit two applications for reregistration, each containing all forms and necessary labels. Both applications should be submitted simultaneously. Note that the products will be assigned separate registration numbers.

Item 9B. MISUSE STATEMENT - All products must bear the misuse statement, "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." This statement appears at the beginning of the directions for use, directly beneath the heading of that section.

Item 10A. REENTRY STATEMENT - If a reentry interval has been established by the Agency, it must be included on the label. Additional worker protection statements may be required in accordance with PR Notice 83-2, March 29, 1983.

Item 10B. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix II, STOR, PEST/DIS, and CONT/DIS to determine the storage and disposal instructions appropriate for your products.

Item 10C. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to sue or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. [40 CFR 156.10]

COLLATERAL LABELING

Bulletins, leaflets, circulars, brochures, data sheets, flyers, or other written or graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

SUMMARY-6

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
1	Product name	All products	Front panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for . . .," "Distributed by . . . .," etc.
3	Net contents	All products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units.
4	EPA Reg. No.	All products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Est. No.	All products	None	Front panel immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients statement	All products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/gallon statement	Liquid products where dosage is given as lbs. ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	Note type size requirements.
7B	Signal word	All products	Front panel	Immediately below child hazard warning	Note type size requirements.

SUMMARY-7

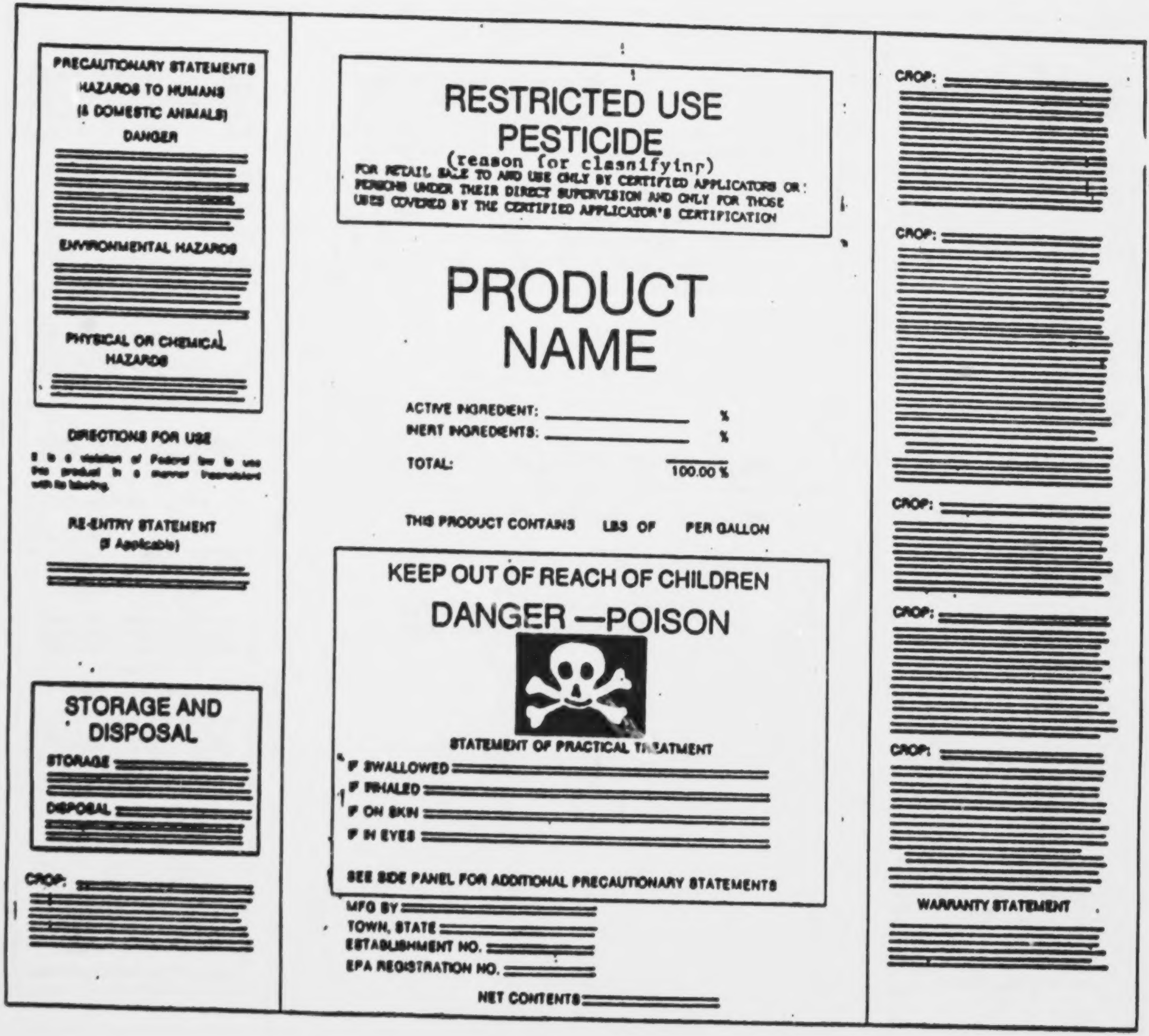
LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED (cont'd)

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
7C	Skull & cross-bones and word POISON (in red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of Practical Treatment or First Aid	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements.	Front panel for all	
7E	Referral statement	All products where precautionary labeling appears on other than front panel	Front panel		
8	Side/back panel precautionary statements	All products	None	Top or side of back panel preceding directions for use	Must be grouped under headings in 8A, 8B, and 8C; preferably blocked.
8A	Hazards to humans and domestic animals	All products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental hazards	All products	None	Same as above	Environmental hazards include bee caution where applicable.

SUMMARY-8

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED (cont'd)

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL REQUIRED	PLACEMENT ON LABEL PREFERRED	COMMENTS
8C	Physical or chemical hazards	All pressurized products, others with flash points under 150°F	None	Same as above	Refer to Appendix II guide PHYS/CHEM
9A	Restricted block	All restricted products	Top center of front panel	Preferably blocked	Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be same type size as signal word.
9B	Misuse statement	All products	Immediately following heading of directions for use		Required statement is: "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."
10A	Reentry statement	PR Notice 83-2 or as determined by the Agency	In the directions for use	Immediately after misuse statement	
10B	Storage and disposal block	All products	In the directions for use	Immediately before specific directions for use or at the end of directions for use	Must be set apart and clearly distinguishable from other directions for use. Refer to Appendix II guides STOR, CONT/DIS, and PEST/DIS for further information and required statements.
10C	Directions for use	All products	None	None	May be in metric as well as U.S. units



PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS
(& DOMESTIC ANIMALS)
DANGER

ENVIRONMENTAL HAZARDS

PHYSICAL OR CHEMICAL
HAZARDS

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

RE-ENTRY STATEMENT
(If Applicable)

STORAGE AND
DISPOSAL

STORAGE:

DISPOSAL:

CROP:

RESTRICTED USE
PESTICIDE
(reason for classifying)
FOR RETAIL SALE TO AND USE ONLY BY CERTIFIED APPLICATORS OR PERSONS UNDER THEIR DIRECT SUPERVISION AND ONLY FOR THOSE USES COVERED BY THE CERTIFIED APPLICATOR'S CERTIFICATION

PRODUCT
NAME

ACTIVE INGREDIENT: ____________ %
INERT INGREDIENTS: ____________ %
TOTAL: 100.00 %

THIS PRODUCT CONTAINS LBS OF PER GALLON

KEEP OUT OF REACH OF CHILDREN
DANGER —POISON

STATEMENT OF PRACTICAL TREATMENT
IF SWALLOWED
IF INHALED
IF ON SKIN
IF IN EYES

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

MFG BY:
TOWN, STATE:
ESTABLISHMENT NO.:
EPA REGISTRATION NO.:

NET CONTENTS:

CROP:

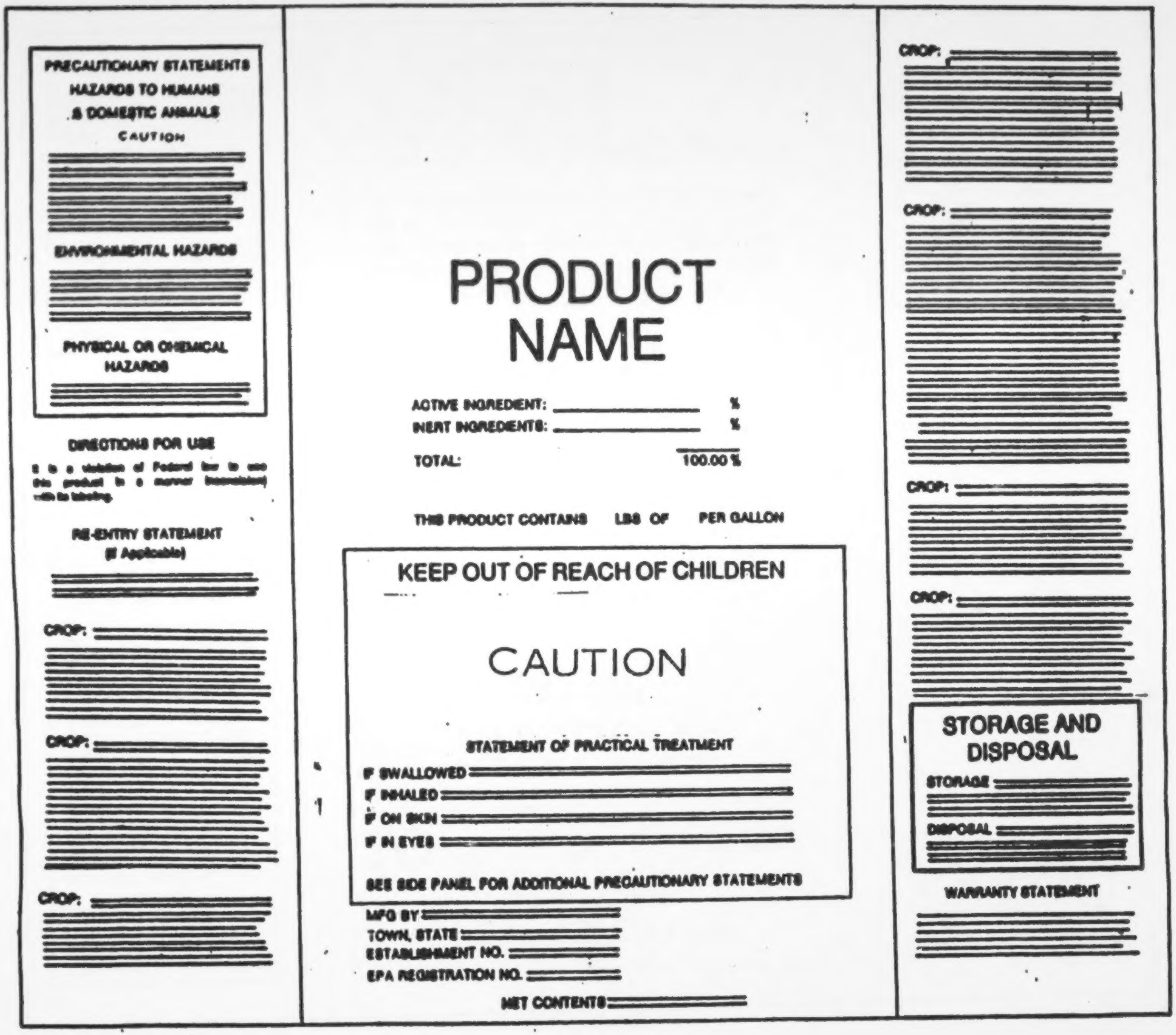
CROP:

CROP:

CROP:

CROP:

WARRANTY STATEMENT



PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS & DOMESTIC ANIMALS
CAUTION

ENVIRONMENTAL HAZARDS

PHYSICAL OR CHEMICAL HAZARDS

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

RE-ENTRY STATEMENT
(If Applicable)

CROP:

CROP:

CROP:

PRODUCT NAME

ACTIVE INGREDIENT: ______ %
INERT INGREDIENTS: ______ %
TOTAL: 100.00 %

THIS PRODUCT CONTAINS LBS OF PER GALLON

KEEP OUT OF REACH OF CHILDREN

CAUTION

STATEMENT OF PRACTICAL TREATMENT

IF SWALLOWED
IF INHALED
IF ON SKIN
IF IN EYES

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

MFG BY
TOWN, STATE
ESTABLISHMENT NO.
EPA REGISTRATION NO.

NET CONTENTS

CROP:

CROP:

CROP:

CROP:

STORAGE AND DISPOSAL

STORAGE

DISPOSAL

WARRANTY STATEMENT

scribed in paragraph (b) of this section;

(ii) The name and address of the producer, registrant, or person for whom produced as prescribed in paragraph (c) of this section;

(iii) The net contents as prescribed in paragraph (d) of this section;

(iv) The product registration number as prescribed in paragraph (e) of this section;

(v) The producing establishment number as prescribed in paragraph (f) of this section;

(vi) An ingredient statement as prescribed in paragraph (g) of this section;

(vii) Warning or precautionary statements as prescribed in paragraph (h) of this section;

(viii) The directions for use as prescribed in paragraph (i) of this section; and

(ix) The use classification(s) as prescribed in paragraph (j) of this section.

(2) *Prominence and legibility.* (i) All words, statements, graphic representations, designs or other information required on the labeling by the Act or the regulations in this part must be clearly legible to a person with normal vision, and must be placed with such conspicuousness (as compared with other words, statements, designs, or graphic matter on the labeling) and expressed in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) All required label text must:

(A) Be set in 6-point or larger type;

(B) Appear on a clear contrasting background; and

(C) Not be obscured or crowded.

(3) *Language to be used.* All required label or labeling text shall appear in the English language. However, the Agency may require or the applicant may propose additional text in other languages as is considered necessary to protect the public. When additional text in another language is necessary, all labeling requirements will be applied equally to both the English and other-language versions of the labeling.

(4) *Placement of Label*—(i) *General.* The label shall appear on or be securely attached to the immediate container of the pesticide product. For purposes of this Section, and the misbranding provisions of the Act, "securely attached" shall mean that a label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. If the immediate container is enclosed within a wrapper or outside container through which the label cannot be clearly read, the label must also be securely attached to such outside wrapper or container, if it is a part of the package as customarily distributed or sold.

(ii) *Tank cars and other bulk containers*—(A) *Transportation.* While a pesticide product is in transit, the appropriate provisions of 49 CFR Parts 170-189, concerning the transportation of hazardous materials, and specifically those provisions concerning the labeling, marking and placarding of hazardous materials and the vehicles carrying them, define the basic Federal requirements. In addition, when any registered pesticide product is transported in a tank car, tank truck or other mobile or portable bulk container, a copy of the accepted label must be attached to the shipping papers, and left with the consignee at the time of delivery.

(B) *Storage.* When pesticide products are stored in bulk containers, whether mobile or stationary, which remain in the custody of the user, a copy of the label of labeling, including all appropriate directions for use, shall be securely attached to the container in the immediate vicinity of the discharge control valve.

(5) *False or misleading statements.* Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to § 162.15, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

(i) A false or misleading statement concerning the composition of the product;

(ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device.

(iii) A false or misleading statement about the value of the product for purposes other than as a pesticide or device;

(iv) A false or misleading comparison with other pesticides or devices;

(v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government;

(vi) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling;

(vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;

(viii) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations;

(ix) Claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous," "noninjurious," "harmless" or "nontoxic to humans and pets" with or without such a qualifying phrase as "when used as directed"; and

(x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:

(A) "Contains all natural ingredients";

(B) "Among the least toxic chemicals known"

(C) "Pollution approved"

(6) *Final printed labeling.* (i) Except as provided in paragraph (a)(6)(ii) of this section, final printed labeling must be submitted and accepted prior to registration. However, final printed labeling need not be submitted until draft label texts have been provisionally accepted by the Agency.

(ii) Clearly legible reproductions or photo reductions will be accepted for unusual labels such as those silk-screened directly onto glass or metal containers or large bag or drum labels. Such reproductions must be of microfilm reproduction quality.

(b) *Name, brand, or trademark.* (1) The name, brand, or trademark under which the pesticide product is sold shall appear on the front panel of the label.

(2) No name, brand, or trademark may appear on the label which:

(i) Is false or misleading, or

(ii) Has not been approved by the Administrator through registration or supplemental registration as an additional name pursuant to § 162.6(b)(4).

(c) Name and address of producer, registrant, or person for whom produced. An unqualified name and address given on the label shall be considered as the name and address of the producer. If the registrant's name appears on the label and the registrant is not the producer, or if the name of the person for whom the pesticide was produced appears on the label, it must be qualified by appropriate wording such as "Packed for * * *," "Distributed by * * *," or "Sold by * * *" to show that the name is not that of the producer.

(d) *Net weight or measure of contents.* (1) The net weight or measure of content shall be exclusive of wrappers or other materials and shall be the average content unless explicitly stated as a minimum quantity.

(2) If the pesticide is a liquid, the net content statement shall be in terms of liquid measure at 68° F (20°C) and shall be expressed in conventional American units of fluid ounces, pints, quarts, and gallons.

(3) If the pesticide is solid or semisolid, viscous or pressurized, or is a mixture of liquid and solid, the net content statement shall be in terms of weight expressed as avoirdupois pounds and ounces.

(4) In all cases, net content shall be stated in terms of the largest suitable units, i.e., "1 pound 10 ounces" rather than "26 ounces."

(5) In addition to the required units specified, net content may be expressed in metric units.

(6) Variation above minimum content or around an average is permissible only to the extent that it represents deviation unavoidable in good manufacturing practice. Variation below a stated minimum is not permitted. In no case shall the average content of the packages in a shipment fall below the stated average content.

(e) *Product registration number.* The registration number assigned to the pesticide product at the time of registration shall appear on the label, preceded by the phrase "EPA Registration No.," or the phrase "EPA Reg. No." The registration number shall be set in type of a size and style similar to other print on that part of the label on which it appears and shall run parallel to it. The registration number and the required identifying phrase shall not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency.

(f) *Producing establishments registration number.* The producing establishment registration number preceded by the phrase "EPA Est.", of the final establishment at which the product was produced may appear in any suitable location on the label or immediate container. It must appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container.

(g) *Ingredient statement*—(1) *General.* The label of each pesticide product must bear a statement which contains the name and percentage by weight of each active ingredient, the total percentage by weight of all inert ingredients; and if the pesticide contains arsenic in any form, a statement of the percentages of total and water-soluble arsenic calculated as elemental arsenic. The active ingredients must be designated by the term "active ingredients" and the inert ingredients by the term "inert ingredients," or the singular forms of these terms when appropriate. Both terms shall be in the same type size, be aligned to the same margin and be equally prominent. The statement "Inert Ingredients, none" is not required for pesticides which contain 100 percent active ingredients. Unless the ingredient statement is a complete analysis of the pesticide, the term "analysis" shall not be used as a heading for the ingredient statement.

(2) *Position of ingredient statement.* (i) The ingredient statement is normally required on the front panel of the label. If there is an outside container or wrapper through which the ingredient statement cannot be clearly read, the ingredient statement must also appear on such outside container or wrapper. If the size or form of the package makes it impracticable to place the ingredient statement on the front panel of the label, permission may be granted for the ingredient statement to appear elsewhere.

(ii) The text of the ingredient statement must run parallel with other text on the panel on which it appears, and must be clearly distinguishable from and must not be placed in the body of other text.

(3) *Names to be used in ingredient statement.* The name used for each ingredient shall be the accepted common name, if there is one, followed by the chemical name. The common name may be used alone only if it is well known. If no common name has been established, the chemical name alone shall be used. In no case will the use of a trademark or proprietary name be permitted unless such name has been accepted as a common name by the Administrator under the authority of section 25(c)(6).

(4) *Statements of percentages.* The percentages of ingredients shall be stated in terms of weight-to-weight. The sum of percentages of the active and the inert ingredients shall be 100. Percentages shall not be expressed by a range of values such as "22-25%." If the uses of the pesticide product are expressed as weight of active ingredient per unit area, a statement of the weight of active ingredient per unit volume of the pesticide formulation shall also appear in the ingredient statement.

(5) *Accuracy of stated percentages.* The percentages given shall be as precise as possible reflecting good manufacturing practice. If there may be unavoidable variation between manufacturing batches, the value stated for each active ingredient shall be the lowest percentage which may be present.

(6) *Deterioration.* Pesticides which change in chemical composition significantly must meet the following labeling requirements:

(i) In cases where it is determined that a pesticide formulation changes chemical composition significantly, the product must bear the following statement in a prominent position on the label: "Not for sale or use after [date]."

(ii) The product must meet all label claims up to the expiration time indicated on the label.

(7) *Inert ingredients.* The Administrator may require the name of any inert ingredient(s) to be listed in the ingredient statement if he determines that such ingredient(s) may pose a hazard to man or the environment.

(h) *Warnings and precautionary statements.* Required warnings and precautionary statements concerning the general areas of toxicological hazard including hazard to children, environmental hazard, and physical or chemical hazard fall into two groups; those required on the front panel of the labeling and those which may appear elsewhere. Specific requirements concerning content, placement, type size, and prominence are given below.

(1) *Required front panel statements.* With the exception of the child hazard warning statement, the text required on the front panel of the label is determined by the Toxicity Category of the pesticide. The category is assigned on the basis of the highest hazard shown by any of the indicators in the table below:

Hazard indicators	Toxicity categories			
	I	II	III	IV
Oral LD_{50}	Up to and including 50 mg/kg.	From 50 thru 500 mg/kg.	From 500 thru 5000 mg/kg.	Greater than 5000 mg/kg.
Inhalation LC_{50}	Up to and including .2 mg/liter.	From .2 thru 2 mg/liter.	From 2. thru 20 mg/liter.	Greater than 20 mg/liter.
Dermal LD_{50}	Up to and including 200 mg/kg.	From 200 thru 2000	From 2,000 thru 20,000	Greater than 20,000.
Eye effects	Corrosive; corneal opacity not reversible within 7 days.	Corneal opacity reversible within 7 days; irritation persisting for 7 days.	No corneal opacity; irritation reversible within 7 days.	No irritation.
Skin effects	Corrosive	Severe irritation at 72 hours.	Moderate irritation at 72 hours.	Mild or slight irritation at 72 hours.

(i) *Human hazard signal word*—(A) *Toxicity Category I.* All pesticide products meeting the criteria of Toxicity Category I shall bear on the front panel the signal word "Danger." In addition if the product was assigned to Toxicity Category I on the basis of its oral, inhalation or dermal toxicity (as distinct from skin and eye local effects) the word "Poison" shall appear in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word "poison."

(B) *Toxicity Category II.* All pesticide products meeting the criteria of Toxicity Category II shall bear on the front panel the signal word "Warning."

(C) *Toxicity Category III.* All pesticide products meeting the criteria of Toxicity Category III shall bear on the front panel the signal word "Caution."

(D) *Toxicity Category IV.* All pesticide products meeting the criteria of Toxicity Category IV shall bear on the front panel the signal word "Caution."

(E) *Use of signal words.* Use of any signal word(s) associated with a higher Toxicity Category is not permitted except when the Agency determines that such labeling is necessary to prevent unreasonable adverse effects on man or the environment. In no case shall more than one human hazard signal word appear on the front panel of a label.

(ii) *Child hazard warning.* Every pesticide product label shall bear on the front panel the statement "keep out of reach of children." Only in cases where the likelihood of contact with children during distribution, marketing, storage or use is demonstrated by the applicant to be extremely remote, or if the nature of the pesticide is such that it is approved for use on infants or small children, may the Administrator waive this requirement.

(iii) *Statement of practical treatment*—(A) *Toxicity Category I.* A statement of practical treatment (first aid or other) shall appear on the front panel of the label of all pesticides falling into Toxicity Category I on the basis of oral, inhalation or dermal toxicity. The Agency may, however, permit reasonable variations in the placement of the statement of practical treatment is some reference such as "See statement of practical treatment on back panel" appears on the front panel near the word "Poison" and the skull and crossbones.

(B) *Other toxicity categories.* The statement of practical treatment is not required on the front panel except as described in paragraph (h)(1)(iii)(A) of this section. The applicant may, however, include such a front panel statement at his option. Statements of practical treatment are, however, required elsewhere on the label in accord with paragraph (h)(2) of this section if they do not appear on the front panel.

(iv) *Placement and prominence.* All the require front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to make them unlikely to be overlooked under customary conditions of purchase and use. The following table shows the minimum type size requirements for the front panel warning statements on various sizes of labels:

Size of label front panel in square inches	Points	
	Required signal word, all capitals	"Keep out of reach of children"
5 and under	6	6
Above 5 to 10	10	6
Above 10 to 15	12	8
Above 15 to 30	14	10
Over 30	18	12

(2) *Other required warnings and precautionary statements.* The warnings and precautionary statements as required below shall appear together on the label under the general heading "Precautionary Statements" and under appropriate subheadings of "Hazard to Humans and Domestic Animals," "Environmental Hazard" and "Physical or Chemical Hazard."

(i) *Hazard to humans and domestic animals.* (A) Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. The precautionary paragraph shall be immediately preceded by the appropriate hazard signal word.

(B) The following table depicts typical precautionary statements. These statements must be modified or expanded to reflect specific hazards.

Toxicity category	Precautionary statements by toxicity category	
	Oral, inhalation, or dermal toxicity	Skin and eye local effects
I	Fatal (poisonous) if swallowed [inhaled or absorbed through skin]. Do not breathe vapor [dust or spray mist]. Do not get in eyes, on skin, or on clothing [Front panel statement of practical treatment required.].	Corrosive, causes eye and skin damage [or skin irritation]. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. [Appropriate first aid statement required.]
II	May be fatal if swallowed [inhaled or absorbed through the skin]. Do not breathe vapors [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Appropriate first aid statements required.].	Causes eye [and skin] irritation. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. [Appropriate first aid statement required.]
III	Harmful if swallowed [inhaled or absorbed through the skin]. Avoid breathing vapors [dust or spray mist]. Avoid contact with skin [eyes or clothing]. [Appropriate first aid statement required.].	Avoid contact with skin, eyes or clothing. In case of contact immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.
IV	[No precautionary statements required.]	[No precautionary statements required.]

(ii) *Environmental hazards.* Where a hazard exists to non target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury or damage. Examples of the hazard statements and the circumstances under which they are required follow:

(A) If a pesticide intended for outdoor use contains an active ingredient with a mammalian acute oral LD_{50} of 100 or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(B) If a pesticide intended for outdoor use contains an active ingredient with a fish acute LC_{50} of 1 ppm or less, the statement "This Pesticide is Toxic to Fish" is required.

(C) If a pesticide intended for outdoor use contains an active ingredient with an avian acute oral LD_{50} of 100 mg/kg or less, or a subacute dietary LC_{50} of 500 ppm or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(D) If either accident history or field studies demonstrate that use of the pesticide may result in fatality to birds, fish or mammals, the statement "This pesticide is extremely toxic to wildlife (fish)" is required.

(E) For uses involving foliar application to agricultural crops, forests, or shade trees, or for mosquito abatement treatments, pesticides toxic to pollinating insects must bear appropriate label cautions.

(F) For all outdoor uses other than aquatic applications the label must bear the caution "Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes."

(iii) *Physical or chemical hazards.* Warning statements on the flammability or explosive characteristics of the pesticide are required as follows:

Flash point	Required text
(A) PRESSURIZED CONTAINERS	
Flash point at or below 20° F; if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
Flash point above 20° F and not over 80° F or if the flame extension is more than 18 in long at a distance of 6 in from the flame.	Flammable. Contents under pressure. Keep away from heat, sparks, and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
All other pressurized containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.
(B) NONPRESSURIZED CONTAINERS	
At or below 20° F	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
Above 20° F and not over 80° F	Flammable. Keep away from heat and open flame.
Above 80° F and not over 150° F	Do not use or store near heat or open flame.

(i) *Directions for Use*—(1) *General requirements*—(i) *Adequacy and clarity of directions.* Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment.

(ii) *Placement of directions for use.* Directions may appear on any portion of the label provided that they are conspicuous enough to be easily read by the user of the pesticide product. Directions for use may appear on printed or graphic matter which accompanies the pesticide provided that:

(A) If required by the Agency, such printed or graphic matter is securely attached to each package of the pesticide, or placed within the outside wrapper or bag;

(B) The label bears a reference to the directions for use in accompanying leaflets or circulars, such as "See directions in the enclosed circular:" and

(C) The Administrator determines that it is not necessary for such directions to appear on the label.

(iii) *Exceptions to requirement for direction for use*—(A) Detailed directions for use may be omitted from labeling of pesticides which are intended for use only by manufacturers of products other than pesticide products in their regular manufacturing processes, provided that:

(*1*) The label clearly shows that the product is intended for use only in manufacturing processes and specifies the type(s) of products involved.

(*2*) Adequate information such as technical data sheets or bulletins, is available to the trade specifying the type of product involved and its proper use in manufacturing processes;

(*3*) The product will not come into the hands of the general public except after incorporation into finished products; and

(*4*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(B) Detailed directions for use may be omitted from the labeling of pesticide products for which sale is limited to physicians, veterinarians, or druggists, provided that:

(*1*) The label clearly states that the product is for use only by physicians or veterinarians;

(*2*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment; and

(*3*) The product is also a drug and regulated under the provisions of the Federal Food, Drug and Cosmetic Act.

(C) Detailed directions for use may be omitted from the labeling of pesticide products which are intended for use only by formulators in preparing pesticides for sale to the public, provided that:

(*1*) There is information readily available to the formulators on the composition, toxicity, methods of use, applicable restrictions or limitations, and effectiveness of the product for pesticide purposes;

(*2*) The label clearly states that the product is intended for use only in manufacturing, formulating, mixing, or repacking for use as a pesticide and specifies the type(s) of pesticide products involved;

(*3*) The product as finally manufactured, formulated, mixed, or repackaged is registered; and

(*4*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(2) *Contents of Directions for Use.* The directions for use shall include the following, under the headings "Directions for Use":

(i) The statement of use classification as prescribed in 162.10(j) immediately under the heading "Directions for Use."

(ii) Immediately below the statement of use classification, the statement "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

(iii) The site(s) of application, as for example the crops, animals, areas, or objects to be treated.

(iv) The target pest(s) associated with each site.

(v) The dosage rate associated with each site and pest.

(vi) The method of application, including instructions for dilution, if required, and type(s) of application apparatus or equipment required.

(vii) The frequency and timing of applications necessary to obtain effective results without causing unreasonable adverse effects on the environment.

(viii) Specific limitations on reentry to areas where the pesticide has been applied, meeting the requirements concerning reentry provided by 40 CFR Part 170.

(ix) Specific directions concerning the storage and disposal of the pesticide and its container, meeting the requirements of 40 CFR Part 165. These instructions shall be grouped and appear under the heading "Storage and Disposal." This heading must be set in type of the same minimum sizes as required for the child hazard warning. (See Table in § 162.10(h)(1)(iv))

(x) Any limitations or restrictions on use required to prevent unreasonable adverse effects, such as:

(A) Required intervals between application and harvest of food or feed crops.

(B) Rotational crop restrictions.

(C) Warnings as required against use on certain crops, animals, objects, or in or adjacent to certain areas.

(D) [Reserved]

(E) For restricted use pesticides, a statement that the pesticide may be applied under the direct supervision of a certified applicator who is not physically present at the site of application but nonetheless available to the person applying the pesticide, unless the Agency has determined that the pesticide may only be applied under the direct supervision of a certified applicator who is physically present.

(F) Other pertinent information which the Administrator determines to be necessary for the protection of man and the environment.

(j) *Statement of Use Classification.* By October 22, 1976, all pesticide products must bear on their labels a statement of use classification as described in paragraphs (j) (1) and (2) of this section. Any pesticide product for which some uses are classified for general use and others for restricted use shall be separately labeled according to the labeling standards set forth in this subsection, and shall be marketed as separate products with different registration numbers, one bearing directions only for general use(s) and the other bearing directions for restricted use(s) except that, if a product has both restricted use(s) and general use(s), both of these uses may appear on a product labeled for restricted use. Such products shall be subject to the provisions of § 162.10(j)(2).

(1) *General Use Classification.* Pesticide products bearing directions for use(s) classified general shall be labeled with the exact words "General Classification" immediately below the heading "Directions for Use." And reference to the general classification that suggests or implies that the general utility of the pesticide extends beyond those purposes and uses contained in the Directions for Use will be considered a false or misleading statement under the statutory definitions of misbranding.

(2) *Restricted Use Classification.* Pesticide products bearing direction for use(s) classified restricted shall bear statements of restricted use classification on the front panel as described below:

(i) *Front panel statement of restricted use classification.* (A) At the top of the front panel of the label, set in type of the same minimum sizes as required for human hazard signal words (see table in § 162.10(h)(1)(iv)), and appearing with sufficient prominence relative to other text and graphic material on the front panel to make it unlikely to be overlooked under customary conditions of purchase and use, the statement "Restricted Use Pesticide" shall appear.

(B) Directly below this statement on the front panel, a summary statement of the terms of restriction imposed as a precondition to registration shall appear. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification." If, however, other regulatory restrictions are imposed, the Administrator will define the appropriate wording for the terms of restriction by regulation.

(k) Advertising. [Reserved]

[40 FR 28268, July 3, 1975; 40 FR 32329, Aug. 1, 1975; 40 FR 36571, Aug. 21, 1975, as amended at 43 FR 5786, Feb. 9, 1978]

~~§ 162.11 Criteria for determinations of unreasonable adverse effects.~~

~~(a)–(b) [Reserved]~~

~~(c) *Use classification*—(1) *Classification criteria for new registrations.* Except as provided in paragraph (c)(4) of this section, a specific use(s) of a pesticide product not previously registered shall be classified for general use if each of the applicable criteria set forth in paragraph (c)(1)(i) through (iii) of this section is met. Otherwise, the product use(s) shall be classified for restricted use unless a review of the labeling pursuant to paragraph (c)(3) of this section indicates that the product use may be classified for general use or the benefits from unrestricted use of the pesticide outweigh the risks of unrestricted use of the pesticide. Each of the separate criteria as set forth below must be applied for the product use(s) to be classified~~

PHYSICAL-CHEMICAL HAZARDS

Criteria	Required Label Statement
I. Pressurized Containers	
A. Flashpoint at or below 20°F; or if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
B. Flashpoint above 20°F and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
C. ALL OTHER PRESSURIZED CONTAINERS	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
II. Non-Pressurized Containers	
A. Flashpoint at or below 20°F.	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20°F and not over 80°F.	Flammable. keep away from heat and open flame.
C. Flashpoint over 80°F and not over 150°F.	Do not use or store near heat and open flame.
D. Flashpoint above 150°F.	None required.

STOR-1

STORAGE INSTRUCTIONS FOR PESTICIDES

Heading:

All products are required to bear specific label instructions about storage and disposal. Storage and disposal instructions must be grouped together in the directions for use portion of the label under the heading STORAGE AND DISPOSAL. Products intended solely for domestic use need not include the heading "STORAGE AND DISPOSAL."

Storage Instructions:

All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.
2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.
3. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.
4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.
5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.
6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

PESTICIDE DISPOSAL INSTRUCTIONS

The label of all products, except those intended solely for domestic use, must bear explicit instructions about pesticide disposal. The statements listed below contain the exact wording that must appear on the label of these products:

1. The labels of all products, except domestic use, must contain the statement, "Do not contaminate water, food, or feed by storage or disposal."

2. Except those products intended solely for domestic use, the labels of all products that contain active ingredients that are Acute Hazardous Wastes or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, or Toxicity Category I or II on the basis of acute inhalation toxicity must bear the following pesticide disposal statement:

> "Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

3. The labels of all products, except those intended for domestic use, containing active or inert ingredients that are Toxic Hazardous Wastes or meet any of the criteria in 40 CFR 261, Subpart C for a hazardous waste must bear the following pesticide disposal statement:

> "Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

4. Labels for all other products, except those intended for domestic use, must bear the following pesticide disposal statement:

> "Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

5. Products intended for domestic use only must bear the following disposal statement: "Securely wrap original container in several layers of newspaper and discard in trash."

CONT/DIS-1

CONTAINER DISPOSAL INSTRUCTIONS

The label of each product must bear container disposal instructions appropriate to the type of container.

1. Domestic use products must bear one of the following container disposal statements:

Container Type	Statement
Non-aerosol products (bottles, cans, jars)	Do not reuse container (bottle, can, jar). Rinse thoroughly before discarding in trash.
Non-aerosol products (bags)	Do not reuse bag. Discard bag in trash.
Aerosol products	Replace cap and discard containers in trash. Do not incinerate or puncture.

2. All other products must bear container disposal instructions, based on container type, listed below:

Container Type	Statement
Metal containers (non-aerosol)	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.
Plastic containers	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
Glass containers	Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.
Fiber drums with liners	Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused[1]/, dispose of in the same manner.
Paper and plastic bags	Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Compressed gas cylinders	Return empty cylinder for reuse (or similar wording).

[1]/ Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

III. BIBLIOGRAPHY APPENDICES

Guide to Use of This Bibliography

1. CONTENT OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Standard. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, will be included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by "Master Record Identifier," or MRID, number. This number is unique to the citation, and should be used at any time specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. These entries are listed after all MRID entries. This temporary identifier number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

    a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first submitter as author.

b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing Parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

    (1) Submission Date. The date of the earliest known submission appears immediately following the word "received."

    (2) Administrative Number. The next element, immediately following the word "under," is the registration number, experimental use permit number, petition number or other administrative number associated with the earliest known submission.

    (3) Submitter. The third element is the submitter, following the phrase "submitted by." When authorship is defaulted to the submitter, this element is omitted.

    (4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," standing for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting Registrations Under the Methomyl Standard

MRID	CITATION
00006995	Shell Chemical Company (1976) 1975--Residue Data for Nudrin Insecticide in Bell Peppers Resulting from the Application of Nudrin, a California Study: TIR-24-240-75. (Unpublished study received Jun 29, 1976 under 201-347; CDL:232402-A)
00006996	Shell Chemical Company (1976) 1975--Residue Data for Nudrin Insecticide in Green Peppers Resulting from the Application of Nudrin, an Iowa Study: TIR-24-268-75. (Unpublished study received Jun 29, 1976 under 201-347; CDL:232402-B)
00007001	Shell Chemical Company (1976) 1975--Residue Data for Nudrin Insecticide in Spinach Resulting from the Application of Nudrin from Modesto, California: TIR-24-137-75. (Unpublished study including TIR-24-280-75, received Jun 29, 1976 under 201-347; CDL: 232402-I)
00007002	Shell Chemical Company (1975) 1974--Residue Data for Nudrin Insecticide in Spinach Following Application of Nudrin from Yakima, Washington: TIR-24-147-74. (Unpublished study received Jun 29, 1976 under 201-347; CDL:232402-J)
00007003	Shell Chemical Company (1976) 1975--Residue Data for Nudrin Insecticide in Spinach Resulting from the Application of Nudrin, a Tennessee Study: TIR-24-363-75. (Unpublished study received Jun 29, 1976 under 201-347; CDL:232402-K)
00007004	Shell Chemical Company (1975) 1974--Residue Data for Nudrin Insecticide in Sugar Beets Following Application of Nudrin from Williams, California: TIR-24-177-74. (Unpublished study including TIR-24-184-74 and TIR-24-247-74, received Jun 29, 1976 under 201-347; CDL:232402-L)
00007005	Shell Chemical Company (1975) 1975--Residue Data for Nudrin Insecticide in Tobacco Leaves Resulting from the Application of Nudrin from Rocky Mtn., North Carolina: TIR-24-217-75. (Unpublished study received Jun 29, 1976 under 201-347; CDL:232402-M)
00007007	Shell Chemical Company (1975) 1975—Residue Data for Nudrin Insecticide in Tomatoes Resulting from the Application of Nudrin from Homestead, Florida: TIR-24-118-75. (Unpublished study received Jun 29, 1976 under 201-347; CDL:232402-O)
00007008	Shell Chemical Company (1975) 1974--Residue Data for Nudrin Insecticide in Soybeans Resulting from the Application of Nudrin from Tallasee, Alabama: TIR-24-103-75. (Unpublished study received Jun 29, 1976 under 201-347; CDL:232402-P)

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MRID CITATION

00007039 E.I. du Pont de Nemours & Company (1972) Residue Data. (Unpublished study received Jan 22, 1973 under 352-370; CDL:101340-A)

00007043 Wellman, D.; Kiigemagi, U.; Terriere, L.C. (1971) Residues of Methomyl in Peppermint Hay and Oil. (Unpublished study received Jun 13, 1972 under 3E1303; prepared by Oregon State Univ., Dept. of Agricultural Chemistry, submitted by Interregional Research Project No. 4, New Brunswick, N.J.; CDL:092205-C)

00007044 Wellman, D.; Cooley, E.J.; Kiigemagi, U.; Terriere, L.C. (1972) Residues of Methomyl in Mint Hay and Oil. (Unpublished study received Jun 13, 1972 under 3E1303; prepared by Oregon State Univ., Dept. of Agricultural Chemistry, submitted by Interregional Research Project No. 4, New Brunswick, N.J.; CDL: 092205-D)

00007077 E.I. du Pont de Nemours & Company (1971) Residue Data: Methomyl--Apples. (Unpublished study received Mar 5, 1974 under 3F1308; CDL:092222-AW)

00007081 E.I. du Pont de Nemours and Company (1971) Results of Tests on the Amount of Residue Remaining on Treated Crops: Methomyl (Unpublished study received Apr 26, 1971 under 1F1158; CDL: 090951-F)

00007091 Busey, W.M. (1968) Final Report: Two-year Dietary Administration--Dogs: Project No. 201-165. (Unpublished study including addendum, received Jun 5, 1969 under 9F0814; prepared by Hazleton Laboratories, Inc., submitted by E.I. du Pont de Nemours & Co., Inc., Wilmington, Del.; CDL:091405-A)

00007093 Kundzin, M. (1968) Three-Generation Reproduction Study: Lannate Methomyl Insecticide: Final Report: Project No. 201-166. (Unpublished study received Jun 5, 1969 under 9F0814; prepared by Hazleton Laboratories, Inc., submitted by E.I. du Pont de Nemours & Co., Inc., Wilmington, Del.; CDL:091405-C)

00007094 E.I. du Pont de Nemours & Company (1969) Results of Tests on the Amount of Residue Remaining on Treated Crops: Methomyl. (Unpublished study received Jun 5, 1969 under 9F0814; CDL:091405-D)

00007132 Shell Development Company (1975) Residue Determination of Nudrin Insecticide in Crops: GLC-Flame Photometric Detector Method: Modesto Method Series. Method MMS-R-427-1 dated May 1975. (Unpublished study received Jun 29, 1976 under 201-347; CDL:232400-C)

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MRID	CITATION
00007133	Shell Chemical Company (1976) 1974--Residue Data for Nudrin Insecticide in Alfalfa Resulting from the Application of Nudrin, a Colorado Study: TIR-24-199-74. (Unpublished study received Jun 29, 1976 under 201-347; CDL:232400-E)
00007134	Shell Chemical Company (1975) 1974--Residue Data for Nudrin Insecticide in Snap Beans Following Application of Nudrin from Modesto, California: TIR-24-151-74. (Unpublished study including TIR-24-163-74, TIR-24-213-74, TIR-24-271-74 and TIR-24-117-75, received Jun 29, 1976 under 201-347; CDL:232400-G)
00007135	Shell Chemical Company (1976) 1974--Residue Data for Nudrin Insecticide in Pinto Beans Resulting from the Application of Nudrin, a Colorado Study: TIR-24-200-74. (Unpublished study including TIR-24-265-75, received Jun 29, 1976 under 201-347; CDL:232400-I)
00007136	Shell Chemical Company (1975) 1975--Residue Data for Nudrin Insecticide in Celery Resulting from the Application of Nudrin from Lake Harbour, Florida: TIR-24-128-75. (Unpublished study received Jun 29, 1976 under 201-347; CDL:232400-M)
00007137	Shell Chemical Company (1975) 1975--Residue Data for Nudrin Insecticide in Grapefruit Resulting from the Application of Nudrin from Weslaco, Texas: TIR-24-155-75. (Unpublished study including TIR-24-159-75 and TIR-24-161-75, received Jun 29, 1976 under 201-347; CDL:232400-O)
00007138	Shell Chemical Company (1975) 1974--Residue Data for Nudrin Insecticide in Lemons from Fort Pierce, Florida: TIR-24-268-74. (Unpublished study including TIR-24-157-75, received Jun 29, 1976 under 201-347; CDL:232400-P)
00007139	Shell Chemical Company (1975) 1975--Residue Data for Nudrin Insecticide in Oranges Following Application of Nudrin from Modesto, California: TIR-24-115-75. (Unpublished study including TIR-24-158-75, received Jun 29, 1976 under 201-347; CDL:232400-R)
00007140	Shell Chemical Company (1975) 1975--Residue Data for Nudrin Insecticide in Tangerines Following Application of Nudrin from Modesto, California: TIR-24-114-75. (Unpublished study received Jun 29, 1976 under 201-347; CDL:232400-T)

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MRID	CITATION
00007142	Shell Chemical Company (1976) 1974--Residue Data for Nudrin(R) Insecticide in Sweet Corn Resulting from the Application of Nudrin, an Illinois Study: TIR-24-181-74. (Unpublished study including TIR-24-186-75, TIR-24-311-75 and TIR-24-329-75, received Jun 29, 1976 under 201-347; CDL:232400-AAA)
00007159	E.I. du Pont de Nemours and Company (1973) Methomyl Residues--Alfalfa. (Unpublished study received May 11, 1973 under 352-342; CDL:008508-A)
00007161	E.I. du Pont de Nemours and Company (1973) Supplemental Data Supporting the Use of Lannate Methomyl Insecticide on Sugar Beets. Summary of studies 008509-B through 008509-G. (Unpublished study received May 15, 1973 under 352-342; CDL:008509-A)
00007168	E.I. du Pont de Nemours and Company (1973) Data Supporting the Aerial Use of Lannate Methomyl Insecticide and Lannate L Methomyl Insecticide. (Unpublished study received May 24, 1973 under 352-342; CDL:008511-A)
00007175	E.I. du Pont de Nemours & Company (1971) Methomyl Residue Data: Lettuce. (Unpublished study received Jan 12, 1971 under 352-342; CDL:106655-E)
00007185	E.I. du Pont de Nemours and Company (1971) Data Supporting the Use of Lannate on Spinach. Summary of studies 003029-B through 003029-D, 003029-F through 003029-I, and 003029-K through 003029-Q. (Unpublished study received Nov 16, 1971 under 352-342; CDL:003029-A)
00007192	E.I. du Pont de Nemours & Company (1974) Data Supporting the Use of Lannate Methomyl Insecticide and Lannate L Methomyl Insecticide on Onions. Summary of studies 026715-B through 026715-D, 026715-G through 026715-N. (Unpublished study received Jul 30, 1974 under 352-370; CDL:026715-A)
00007604	Shell Chemical Company (1976) 1976--Residue Data for Nudrin Insecticide in Broccoli Resulting from the Application of Nudrin, a California Study: TIR-24-100-76. (Unpublished study received Jun 29, 1976 under 201-347; CDL:232400-U)
00007605	Shell Chemical Company (1976) 1976--Residue Data for Nudrin Insecticide in Cauliflower Resulting from the Application of Nudrin, a California Study: TIR-24-105-76. (Unpublished study received Jun 29, 1976 under 201-347; CDL:232400-V)

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MRID	CITATION
00007612	E.I. du Pont de Nemours & Company (1975) Results of Tests on the Amount of Residue Remaining on Treated Crops: Methomyl. (Unpublished study received Apr 8, 1975 under 5F1615; CDL:094495-B)
00007626	E.I. du Pont de Nemours & Company (1974) Results of Tests on the Amount of Residue Remaining on Treated Crops: Methomyl. (Unpublished study received Apr 8, 1975 under 5F1616; CDL:094496-B)
00007634	E.I. du Pont de Nemours and Company (1973) Results of Tests on the Amount of Residue Remaining on Treated Crops: Methomyl. (Unpublished study received on unknown date under 4F1437; CDL: 093831-A)
00007659	E.I. du Pont de Nemours and Company (1967) Results of Tests on the Amount of Residue Remaining on Treated Crop: Methomyl. (Unpublished study received Dec 28, 1968 under 8F0677; CDL: 091184-A)
00007672	E.I. du Pont de Nemours and Company (1972) Results of Tests on the Amount of Residue Remaining on Treated Crops: Methomyl. (Unpublished study received Sep 1, 1972 under 2F1246; CDL:091770-A)
00007683	E.I. du Pont de Nemours and Company (1972) Results of Tests on the Amount of Residue Remaining on Treated Crops: Lannate. (Unpublished study received Sep 2, 1972 under 2F1247; CDL:091771-A)
00007690	E.I. du Pont de Nemours and Company (1973) Data Supporting the Use of Lannate Methomyl Insecticide on Cotton. Summary of studies 003043-B through 003043-U. (Unpublished study received Mar 1, 1973 under 352-342; CDL:003043-A)
00007715	WARF Institute, Incorporated (1973) Residue Summary--WARF Data. (Unpublished study including WARF Institute nos. 3020936-69 and 3020936-0952, received Apr 5, 1973 under 201-347; submitted by Shell Chemical Co., Washington, D.C.; CDL:001053-G)
00007832	E.I. du Pont de Nemours & Company (1974) Data Supporting the Use of Lannate and Lannate L Methomyl Insecticide on Nectarines. Summary of studies 009832-B through 009832-E. (Unpublished study received Mar 4, 1974 under 352-342; CDL:009832-A)
00007837	E.I. du Pont de Nemours & Company (1974) Data Supporting the Use of Lannate Methomyl Insecticide and Lannate L Methomyl Insecticide on Carrots. Summary of studies 028450-B through 028450-G. (Unpublished study received Dec 20, 1974 under 352-342; CDL:028450-A)

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00007947 Dashiell, O.L. (1971) Acute Skin Absorption LD50 Test in Rabbits: Haskell Laboratory Report No. 340-71. (Unpublished study received Sep 1, 1972 under 2F1245; submitted by E.I. du Pont de Nemours & Co., Inc., Wilmington, Del.; CDL:091769-B)

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00007991 Shell Chemical Company (1975) 1974--Residue Data for Nudrin Insecticide in Grapes from Modesto, California: TIR-24-161-74. (Unpublished study received Jun 29, 1976 under 201-347; CDL: 232401-I)

00007992 Shell Chemical Company (1975) 1975--Residue Data for Nudrin Insecticide in Lettuce Resulting from the Application of Nudrin from Arvin, California: TIR-24-214-74. (Unpublished study received Jun 29, 1976 under 201-347; CDL:232401-J)

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00007997 Shell Chemical Company (1975) 1974--Residue Data for Nudrin Insecticide in Peanuts from Pontotox, Texas: TIR-24-241-74. (Unpublished Study received Jun 29, 1976 under 201-347; CDL: 232401-Q)

00007999 Shell Chemical Company (1975) 1974--Residue Data for Nudrin Insecticide in Peas Following Application of Nudrin from Modesto, California: TIR-24-126-74. (Unpublished study including TIR-24-154-75 and TIR-24-165-75, received Jun 29, 1976 under 201-347; CDL:232401-U)

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Citations Considered to be Part of the Data Base Supporting Registrations Under the Methomyl Standard

MRID	CITATION
00008039	Shell Chemical Company (1975) 1974--Residue Data for Nudrin Insecticide in Alfalfa Following Application of Nudrin from Reno, Nevada: TIR-24-142-74. (Unpublished study including TIR-24-153-74, TIR-24-166-74, TIR-24-167-74, TIR-24-175-74 and TIR-24-803-74, received Mar 31, 1975 under 201-347; CDL:115269-AP)
00008043	E.I. du Pont de Nemours & Company (1968) Recovery Studies: Methomyl--Leafy Vegetables. (Unpublished study received Mar 31, 1975 under 201-347; submitted by Shell Chemical Co., Washington, D.C.; CDL:115269-AY)
00008044	E.I. du Pont de Nemours and Company (1972) Data Supporting the Use of Lannate Methomyl Insecticide on Sugar Beets. Summary of studies 003036-B through 003036-I, 003036-K through 003036-P, and 003036-R through 003036-T. (Unpublished study received Mar 6, 1972 under 352-342; CDL:003036-A)
00008145	E.I. du Pont de Nemours and Company (1974) Data Supporting the Use of Lannate Methomyl Insecticide and Lannate L Methomyl Insecticide on Corn. Summary of studies 023294-A through 023294-G and 023294-I through 023294-Q. (Unpublished study received Mar 5, 1974 under 352-342; CDL:023294-A)
00008154	E.I. du Pont de Nemours & Company (1974) Supplemental Data Supporting the Use of Lannate and Lannate L Methomyl Insecticides on Peas. Summary of studies 023301-B through 023301-G and 023301-I through 023301-L. (Unpublished study received Mar 5, 1974 under 352-342; CDL:023301-A)
00008233	E.I. du Pont de Nemours & Company (1974) Summary of Residues on Sorghum and Lannate Methomyl Insecticide for Control of Southwestern Corn Borer and Corn Earworm on Grain Sorghum. Summary of studies 009653-B, 009653-D through 009653-F, 009653-I through 009653-K, 009653-M, and 009653-O through 009653-Q. (Unpublished study received Dec 20, 1974 under 352-342; CDL:009653-A)
00008264	E.I. du Pont de Nemours & Company (1971) Supplemental Information: Methomyl. (Unpublished study received Jun 16, 1971 under 1F1021; CDL:091071-A)
00008295	E.I. du Pont de Nemours and Company (1969) Results of Tests on the Amount of Residue Remaining on Treated Crops: Methomyl. (Unpublished study received Jan 21, 1970 under 0F0886; CDL:091530-L)

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MRID	CITATION
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IV. FORMS APPENDICES

OMB Approval No. 2070-0057
Expires 11/30/89

FIFRA SECTION 3(C)(2)(B) SUMMARY SHEET	**EPA REGISTRATION NO.**
PRODUCT NAME	
APPLICANT'S NAME	**DATE GUIDANCE DOCUMENT ISSUED**

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(C)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner:

☐ 1. I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use:

☐ 2. I have entered into an agreement with one or more other registrants under FIFRA section 3(C)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by:

NAME OF OTHER REGISTRANT

☐ 3. I enclose a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements:

☐ 4. I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products):

☐ 5. I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)

REGISTRANT'S AUTHORIZED REPRESENTATIVE	**SIGNATURE**	**DATE**

EPA Form 8580-1

EPA	US Environmental Protection Agency Washington, DC 20460 **Product Specific Data Report**	Registration Standard for:	EPA Registration Number	Form Approved OMB #2070-0057 Expires 11-30-89

Registration Guideline No.	Name of Test	Testing not required for my product listed above (Check below)	I am complying with Data Requirements by -		(For EPA Use Only) Accession numbers assigned
			Citing MR ID No.	Submitting Data (Attached) (Check below)	
Sec. 158.120 Product Chemistry					
61-1	Identity of ingredients				
61-2	Statement of composition				
61-3	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk-density, or specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				
63-11	Octanol/water partition coefficient				
63-12	pH				
63-13	Stability				
63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explodability				
63-17	Storage stability				
63-18	Viscosity				
63-19	Miscibility				
63-20	Corrosion Characteristics				
63-21	Dielectric breakdown voltage				
Sec. 158.135 Toxicology					
81-1	Acute oral toxicity, rat				
81-2	Acute dermal toxicity, rabbit				
81-3	Acute inhalation toxicity, rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitization				

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Typed Name and Title	Signature	Date

EPA Form 8580-4 (Rev. 5-88) Previous edition is obsolete.

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CERTIFICATION OF ATTEMPT TO ENTER INTO AN AGREEMENT WITH OTHER REGISTRANTS FOR DEVELOPMENT OF DATA

(To qualify, certify ALL four items)

1. I am duly authorized to represent the following firm(s) who are subject to the requirements of a Notice under FIFRA Section 3(c)(2)(B) contained in a Guidance Document to submit data concerning the active ingredient:	GUIDANCE DOCUMENT DATE ACTIVE INGREDIENT
NAME OF FIRM	**EPA COMPANY NUMBER**

(This firm or group of firms is referred to below as "my firm".)

2. My firm is willing to develop and submit the data as required by that Notice, if necessary. However, my firm would prefer to enter into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing, the following required items or data:

3. My firm has offered in writing to enter into such an agreement. Copies of the offers are attached. That offer was irrevocable and included an offer to be bound by an arbitration decision under FIFRA Section 3(c)(2)(B)(iii) if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

NAME OF FIRM	DATE OF OFFER

However, none of those firm(s) accepted my offer.

4. My firm requests that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) above have agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly inform me whether my firm must submit data to avoid suspension of its registration(s) under FIFRA Section 3(c)(2)(B). (This statement does not apply to applicants for new products.) I give EPA permission to disclose this statement upon request.

TYPED NAME	SIGNATURE	DATE

EPA Form 8580-6

OMB Approval No. 2070-0057
Expiration Date 11/30/89

GENERIC DATA EXEMPTION STATEMENT

EPA Product Registration Number:____________________

Registrant's Name and Address: ____

____

As an authorized representative of the registrant of the product identified above, I certify that:

(1) I have read and am familiar with the terms of the Notice from EPA dated _____________ concerning a requirement for submission of "generic" data on the active ingredient ______________________ named under FIFRA Section 3(c)(2)(B).

(2) My firm requests that EPA not suspend the registration of our product, despite our lack of intent to submit the generic data in question, on the grounds that the product contains the active ingredient solely as the result of the incorporation into the product of another product which contains that active ingredient, which is registered under FIFRA Section 3, and which is purchased by us from another producer.

(3) An accurate Confidential Statement of Formula (CSF) for the above-identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the subject active ingredient in my firm's product, or

The CSF dated___________________ on file with EPA is complete, current and accurate and contains the information requested on the current CSF Form 8570-4. The registered source(s) of the above named active ingredient in my product(s) is/are ________________ and their registration number(s) is/are ____________________.

My firm will apply for an amendment to the registration prior to changing the source of the active ingredient in our product.

(4) I understand, and agree on behalf of my firm, that if at any time any portion of this Statement is no longer true, or if my firm fails to comply with the undertakings made in this Statement, my firm's product's registration may be suspended under FIFRA Section 3(c)(2)(B).

(5) I further understand that if my firm is granted a generic data exemption for the product, my firm relies on the efforts of other persons to provide the Agency with the required generic data. If the registrant(s) who have committed to generate and submit the required data fail to take appropriate steps to meet requirements or are no longer in compliance with this Notice's data requirements, the Agency will consider that both they and my firm are not in compliance and will normally initiate proceedings to suspend the registrations of my firm's product(s) and their product(s), unless my firm commits to submit and submits the required data in the specified time frame. I understand that, in such cases, the Agency generally will not grant a time extension for submitting the data.

Registrant's authorized representative:__________________________________
(Signature

Dated: ____________________ __________________________________
(Typed)

EPA Form 8570-27